

**NATIONAL ENVIRONMENTAL POLICY ACT DECISION  
AND  
FINDING OF NO SIGNIFICANT IMPACT**

Pioneer Hi-Bred International, Inc.  
Insect-Resistant and Herbicide-Tolerant 4114 Maize

United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from the determination requested in the petition (APHIS Number 11-244-01p) by Pioneer Hi-Bred International, Inc. (hereafter referred to as Pioneer). This petition is for non-regulatory status for genetically engineered (GE) Pioneer 4114 Maize<sup>1</sup>, which is an insect-resistant and herbicide-resistant corn product. Insect resistance in Pioneer 4114 Maize is derived from the accumulation of the insecticidal crystalline proteins Cry1F, Cry34Ab1, and Cry 35Ab1 (Pioneer, 2011). This product also incorporates resistance to the herbicide, glufosinate, which is conferred through activity of the PAT protein (Pioneer, 2011). This EA has been prepared to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for 4114 Maize. The EA also assesses alternatives to a determination of nonregulated status of 4114 Maize and analyzes their potential environmental and social effects that may result as a measure for comparison with the proposed action.

---

<sup>1</sup> This product is Pioneer Insect-Resistant and Herbicide-Tolerant 4114 Maize. When referring to the specific product, APHIS uses the term "Maize". When referring to the crop, APHIS uses the more familiar term of "corn". Both "maize" and "corn" are synonyms for the same species, *Zea mays*.

## Regulatory Authority

“Protecting American agriculture” is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can provide enhanced benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest provisions of the Plant Protection Act of 2000 (PPA), as amended (7 USC §§ 7701 *et seq.*) to ensure that they do not pose a plant pest risk to the environment.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of foods derived from GE products.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerances (maximum contaminant levels) for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the FFDCA and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

## **Regulated Organisms**

The APHIS Biotechnology Regulatory Services' (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the PPA or the regulations at 7 CFR 340. The petitioner is required to provide information under §340.6(c) (4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest risk provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

## **The APHIS Response to Petitions for Nonregulated Status**

Under the authority of the plant pest provisions of the PPA and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as 4114 Maize. When a petition for nonregulated status is submitted, APHIS must make a decision on that petition. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the GE organism is unlikely to pose a plant pest risk, then the subject of the petition is no longer subject to its authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

Pioneer has submitted a petition (APHIS Number 11-244-01p) to APHIS seeking a determination that their GE 4114 Maize is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

### **Pioneer Petition for 4114 Maize**

Pioneer submitted this petition for determination of nonregulated status for 4114 Maize to APHIS in 2011. Pioneer 4114 Maize expresses insect-resistant and glufosinate-resistant traits (Pioneer, 2011). The Cry1F, Cry34Ab1 and Cry 35Ab1 proteins are derived from the common

soil bacterium, *Bacillus thuringiensis* (*Bt*). The PAT protein that confers resistance to glufosinate ammonium-based herbicides is derived from a common soil bacterium, *Streptomyces viridochromogene*. The PAT protein acts to convert glufosinate ammonium into its inactive form, thus rendering the plant resistant to glufosinate ammonium (Pioneer, 2011). Pioneer indicates that there will be no change in the use pattern for glufosinate applied to this glufosinate-resistant variety and there will be no need to petition EPA for a change in its label requirement for glufosinate herbicides. APHIS uses current glufosinate-herbicide labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glufosinate.

The herbicide glufosinate ammonium was first registered with the US-EPA in 1993 for home, non-food and farmstead weed control uses (OSTP, 2001), and received its first crop-product registration in 2000 (US-EPA, 2008). The US-EPA has published exemptions for tolerance for both glufosinate and the PAT protein (US-EPA, 2010). Glufosinate is a non-selective foliar herbicide that is used for pre-plant and post-emergence control of broadleaf weeds. Glufosinate inhibits glutamine synthetase. This causes an overproduction of ammonia in tissues resulting in plant death (US-EPA, 2008).

A determination of nonregulated status for 4114 Maize would include 4114 Maize, itself, any progeny derived from crosses between 4114 and conventional corn, and other GE-corn events that have been granted nonregulatory status pursuant to Part 340 and the PPA. If 4114 Maize is no longer regulated, growers and corn seed suppliers would have another variety of corn that expresses Cry1F, Cry34Ab1, Cry 35Ab1 and PAT. Commercial varieties are available that express these traits. They were developed by breeding varieties previously granted nonregulatory status, which express one or more of these transgenes.

Event 4114 Maize is currently regulated under 7 CFR part 340. Interstate movements and field trials of event 4114 Maize have been conducted under permits (3) issued by APHIS, or notifications (16) provided to APHIS from 2006 through 2011. These actions involved twenty states (Arizona, California, Colorado, Delaware, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, Oklahoma, Pennsylvania, South Dakota, Tennessee, Texas, and Wisconsin) and Puerto Rico. Data resulting from these field trials are described in the petition (Pioneer, 2011).

## **Coordinated Framework Review**

### **Food and Drug Administration**

Pioneer 4114 Maize is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. In June 2006, FDA published recommendations in "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (US-FDA, 2011). These recommendations established voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including GE plants. Early food safety evaluations help

make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

On December 23, 2011, Pioneer submitted a safety and nutritional assessment of food and feed derived from 4114 Maize to the FDA (US-FDA Docket Number BNF 136). FDA completed its evaluation on March 25, 2013.

## **Environmental Protection Agency**

As described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011a). Registration decisions are based on scientific studies that assess a chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered by EPA, must be reregistered every 15 years to ensure that they meet current, more stringent standards (US-EPA, 2011a). The reregistration review was started for glufosinate in 2008 (US-EPA, 2011b). Before a pesticide can be used on a food or feed crop, the EPA must establish a maximum contaminant level or tolerance, which is the maximum amount of pesticide residue that can remain on a crop or in foods or feed processed from a crop (US-EPA, 2011d). Pesticide tolerances for glufosinate on corn have been published in the *Federal Register*, 40 CFR §180.473, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011c). The glufosinate tolerances for corn are as follows: field corn intended for forage, 4.0 parts per million (ppm); corn stover, 6.0 ppm; grain corn, 0.20 ppm (40 CFR §180.473).

The EPA regulates plant-incorporated protectants under FIFRA, and certain biological control organisms under TSCA. The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. Pioneer 4114 Maize was registered with EPA on June 7, 2012.

## **Scope of the Environmental Analysis**

Although a determination of nonregulated status of 4114 Maize would allow for new plantings of 4114 Maize anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support corn production. A determination of nonregulated status of 4114 Maize is not expected to promote an increase in corn production by its availability alone, or in combination with other factors, nor is it likely to cause an increase in overall GE-corn acreage. To identify major areas of corn production, APHIS used data from the National Agricultural Statistics Service (USDA-NASS, 2010) to determine where corn is produced in the U.S. (USDA-NASS, 2010). Corn is primarily produced in an area of the U.S. commonly known as the Corn Belt, which includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri. These ten states accounted for approximately 73 percent of the nation's corn production in 2011 (USDA-NASS, 2012a, 2012d).

## Public Involvement

On February 27, 2013, APHIS published a notice in the *Federal Register* (77 FR 41353-41354, Docket no. APHIS-2012-0046) announcing the availability of the Pioneer petition for a 60-day public review and comment period. Comments were required to be received on or before April 29, 2013. All comments were carefully reviewed to identify new issues, alternatives, or information. A total of 573 comments<sup>2</sup> were received from the comment period, of which 561 were form letters. Most comments did not describe substantive specific disagreement with the APHIS analysis of 4114 Maize detailed in the EA or PPRA (USDA-APHIS, 2012a). They did instead express general opposition to genetically modified organisms (GMOs) or GE crops. No new issues or alternatives conveying new information were identified in the comments received by APHIS. Responses to substantive comments received by APHIS are included as an attachment to this FONSI.

## Major Issues Addressed in the EA

The issues considered in the EA were developed based on the specific petition seeking a determination of nonregulated status for 4114 Maize, and the basis for previous APHIS determinations that certain GE organisms are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for 4114 Maize. Issues discussed in the EA were developed by considering public concerns as well as those identified in public comments submitted for other environmental assessments of GE organisms, concerns detailed in lawsuits, and those issues that have been described by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods, and the environmental food/feed safety of GE plants were addressed to analyze the potential environmental impacts of 4114 Maize.

The list of resource areas considered were developed by APHIS through experience in considering public concerns and issues in public comments submitted for other EAs of GE organisms. The resource areas considered also address concerns identified in previous and unrelated lawsuits, as well as issues that have been described by various stakeholders in the past. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These resource areas can be categorized as follows:

### Agricultural Production Considerations:

- Acreage and Areas of Corn Production
- Agronomic/Cropping Practices

---

<sup>2</sup> . Comment documents may be viewed at:  
[http://www.regulations.gov/#!searchResults;rpp=50;so=ASC;sb=docId;po=0;s=APHIS-2012-0026\\_](http://www.regulations.gov/#!searchResults;rpp=50;so=ASC;sb=docId;po=0;s=APHIS-2012-0026_)

- Corn Seed Production
- Organic Corn Production

#### Environmental Considerations:

- Water Resources
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Gene Flow
- Microorganisms
- Biological Diversity

#### Human Health Considerations:

- Public Health
- Worker Safety

#### Livestock Health Considerations:

- Livestock Health/Animal Feed

#### Socioeconomic Considerations:

- Domestic Economic Environment
- Organic Farming
- Trade Economic Environment

### **Alternatives That Were Fully Analyzed**

The EA analyzes the potential environmental consequences of a determination of nonregulated status of 4114 Maize. To respond favorably to a petition for nonregulated status, APHIS must determine that 4114 Maize is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2012a), APHIS has concluded that 4114 Maize is unlikely to pose a plant pest risk. Therefore, APHIS must determine that 4114 Maize is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of 4114 Maize. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of this EA.

### **No Action: Continuation as a Regulated Article**

Under the No Action Alternative, APHIS would deny the petition. 4114 Maize and progeny derived from 4114 Maize would continue to be regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of 4114 Maize and measures to ensure physical and reproductive confinement

would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of 4114 Maize.

This alternative is not the preferred alternative because APHIS has concluded through a PPRA that 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Therefore, this alternative would not satisfy the purpose and need of making a determination of plant pest risk status required for denial of the petition for nonregulated status.

### **Preferred Alternative: Determination that 4114 Maize is No Longer a Regulated Article**

Under this alternative, 4114 Maize and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of 4114 Maize and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of 4114 Maize, is not expected to increase corn production, either by its availability alone or associated with other factors, and therefore will not result in an increase in overall acreage of GE corn. Potential impacts would be similar to the No Action Alternative. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that 4114 Maize is unlikely to pose a plant pest risk, a determination of nonregulated status of 4114 Maize is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

### **Alternatives Considered but Rejected from Further Consideration**

APHIS identified alternatives that might be considered for 4114 Maize. The agency evaluated these alternatives by applying its authority under the PPA and the regulations at 7 CFR part 340, and reviewed issues of environmental safety, efficacy, and practicality to identify those that should be considered for 4114 Maize in a more detailed analysis. Based on this evaluation, APHIS rejected several alternatives. These are described in the sections that follow. Reasons for rejecting each one are also provided.

### **Prohibit any 4114 Maize from Being Released**

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of 4114 Maize, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that 4114 Maize is unlikely to pose a plant health risk (USDA-APHIS, 2012b).

When the PPA was enacted, it included several findings, including the following directive:

“Congress finds that—

“ . . . (4) decisions affecting imports, exports, and interstate movement of products regulated under this title [the Plant Protection Act] shall be based on sound science; . . . ”  
[§402(4)].

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation policies for oversight of emerging technologies (such as genetic engineering) at the agency level. This memorandum directed agencies to implement Executive Order 13563 by adhering to the following principle, among others to the extent permitted by law when regulating emerging technologies:

“Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandate of each agency. . . .”

Based on the PPRA (USDA-APHIS, 2012b), and the scientific data evaluated therein, APHIS concluded that 4114 Maize is unlikely to pose a plant pest risk, so there is no scientific basis for prohibiting the release of 4114 Maize.

### **Approve the Petition in Part**

The regulations at 7 CFR 340.6(d) (3)(i) state that APHIS may “approve the petition in whole or in part.” For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that 4114 Maize is unlikely to pose a plant pest risk, (USDA-APHIS, 2012b) there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

### **Require Isolation and/or Geographic Restriction of 4114 Maize from Non-GE Corn Production**

Because APHIS has concluded that 4114 Maize is unlikely to pose a plant pest risk (USDA-APHIS, 2012b), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating 4114 Maize from conventional or specialty corn production. APHIS also considered geographically restricting the production of 4114 Maize based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in the APHIS plant pest risk assessment for 4114 Maize, there are no geographic differences associated with any identifiable plant pest risks for 4114 Maize (USDA-APHIS, 2012b). This alternative was rejected and not analyzed in detail because APHIS has concluded that 4114 Maize does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with the APHIS statutory authority

under the plant pest provisions of the PPA, regulations in Part 340, and the biotechnology regulatory policies of the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. The agency recognizes that individuals might independently choose to geographically their non-GE corn production systems from 4114 Maize, or to use isolation distances and other management practices to minimize gene movement between 4114 Maize and non-GE corn fields. Information to assist growers in making informed management decisions for 4114 Maize is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

### **Requirement of Testing for 4114 Maize**

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that regulations defining criteria for testing for GE material in non-GE systems, and thresholds for excessive levels have not been established nationally. Because 4114 Maize does not pose a plant pest risk (USDA-APHIS, 2012b), the imposition of any type of requirement for testing it is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies of the Coordinated Framework. Therefore, imposing such a requirement for 4114 Maize would not meet the APHIS purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

### **Environmental Consequences of APHIS' Selected Action**

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
<b>Meets Purpose and Need and Objectives</b>	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2012(USDA-APHIS, 2012a))Satisfied—PPRA (USDA-APHIS, 2012a, 2012b)
<b>Management Practices</b>		
Acreage and Areas of Corn Production	88% of corn grown in U.S. is GE; 49% has stacked herbicide resistance and insect resistance; corn yields are likely to increase.	Unchanged from No Action Alternative
Agronomic Practices	Crop rotation can be effective in controlling some insect pests such as rootworm. Reduced or conservation tillage has largely replaced conventional tillage.	Unchanged from No Action Alternative
Pesticide Use	Insecticide use has declined since the introduction of insect-resistant corn varieties.	Insecticide use will decrease.

Corn Seed Production	Unchanged	Unchanged
Organic Corn Production	Certified organic corn acreage is a small but increasing percentage of overall corn production.	Unchanged from No Action Alternative
<b>Environment</b>		
Land Use	Current trends in the acreage and areas of production are likely to continue to be driven by Federal policy and market conditions (e.g., increased demand for US corn and corn products for animal feed, ethanol, etc.).	Unchanged
Water Resources	The primary cause of agricultural non-point-source pollution is increased soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff	Unchanged from No Action Alternative
Soil	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing corn	Unchanged from No Action Alternative
Air Quality	Agricultural activities such as burning, tilling, harvesting, pesticide and fertilizer applications, and emissions from farm equipment, can directly affect air quality. Aerial application of insecticides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as exhaust emissions from aircraft.	Unchanged from No Action Alternative
Climate Change	Agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production)	Unchanged from No Action Alternative
<b>Animals and Plants</b>		
Animals	Currently available insect-resistant	4114 Maize is not expected to have any

	varieties do not impact vertebrate populations or most invertebrate animals. Some target lepidopteran (e.g., European corn borer) or coleopteran (e.g., corn rootworm) pests. Non-target invertebrates are generally more abundant in <i>Bt</i> cotton and <i>Bt</i> corn fields than in non-transgenic fields managed with chemical insecticides. Currently available glufosinate-resistant varieties do not impact nontarget organisms.	effect on vertebrate animals or most invertebrate animals. 4114 Maize is toxic only to certain coleopteran and lepidopteran insects. Effects on these organisms is unchanged from the No Action Alternative
Plants	Corn fields can be bordered by other agricultural fields (including other corn varieties), woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Corn growers use production practices to manage weeds in and around fields	Unchanged from No Action Alternative
Gene Movement	Cultivated corn varieties can cross-pollinate. Growers use various production practices to limit undesired cross-pollination.	Unchanged from No Action Alternative
Soil Microorganisms	Soil bacterial communities are influenced by plant species and cultivars as well as other environmental factors, such as soil type and agricultural practices. <i>Bt</i> plants may change the soil microbial community when compared to plants that do not express <i>Bt</i> . No deleterious effects have been identified. No effects were observed where glufosinate-resistant plants are cultivated.	Unchanged from No Action Alternative
Biological Diversity	There is no evidence of landscape-level effects from currently available <i>Bt</i> and/or glufosinate-resistant crops. Currently available <i>Bt</i> crops may increase non-target abundance compared to broad-spectrum insecticide use.	Unchanged from No Action Alternative
<b>Human and Animal Health</b>		
Risk to Human Health	Cry proteins of <i>Bt</i> corn products and the PAT protein are not toxic to humans and do not have any known allergenic	Unchanged from No Action Alternative A comprehensive assessment of the safety of 4114 Maize demonstrated that

	<p>properties for humans. 4114 Maize does not have any adverse human health effects. Limited field releases would not result in adverse health effects.</p> <p>Agricultural workers and pesticide applicators would be exposed to a variety of US-EPA-registered pesticides. The EPA's Worker Protection Standard (WPS) (US-EPA, 1992); 40 CFR Part 170.1, <i>Scope and Purpose</i>) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.</p>	<p>the proteins in 4114 are nontoxic to mammals and unlikely to be a food allergen. US-EPA-registered pesticides that are currently used for corn production would continue to be used by growers under the Preferred Alternative. Agricultural production with 4114 Maize does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional corn. Therefore, worker safety issues associated with the agricultural production of 4114 Maize would remain the same as those under the No Action Alternative.</p>
Risk to Animal Feed	<p>Cry proteins and the PAT protein are not expected to be allergenic, toxic, or pathogenic in mammals or poultry. Cry proteins also have a history of safe consumption in the context of other food and feeds.</p>	<p>A compositional analysis concluded that forage and grain from 4114 Maize hybrids are considered similar in composition to forage and grain from both the non-transgenic comparator and conventional corn hybrids. Therefore this is unchanged from the No Action Alternative.</p>
<b>Socioeconomic</b>		
Domestic and Economic Environment	<p>Farm income is positively impacted by currently available <i>Bt</i> and herbicide-resistant corn by reducing production costs or increasing revenues. Pest-resistant corn generally has a positive impact on farm income due to cost savings from reduced pesticide use.</p>	<p>Under the preferred alternative, growers would have an additional tool to use against corn insect pests may reduce economic loss, as well as another tool for herbicide management.</p>
Trade Economic Environment	<p>The primary US corn export destinations are also the largest world importers of corn and do not have major barriers for importing food or feed commodities produced from transgenic crops, including those with insect resistance traits. Nevertheless, import of each specific trait requires separate application and approval by the importing country.</p>	<p>To avoid adversely affecting international trade in corn commodities exported from the US (and Canada), the developer is taking steps to fulfill regulatory requirements for several countries expected to import the product.</p>
<b>Other Regulatory</b>	FDA completed consultations; EPA	FDA completed consultations, EPA tolerance

<b>Approvals</b>	tolerance exemptions and conditional pesticide registrations granted	exemptions and conditional pesticide registrations granted
<b>Compliance with Other Laws</b>		
CWA, CAA, EOs	Fully compliant	Fully compliant

## Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27).

### Context

The term “context” recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic corn production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

In the 2012 production year, corn was cultivated in the United States on approximately 96 million acres, representing a 5% increase in corn acreage from 2011 (USDA-NASS, 2012a). Corn production in 2011 was estimated at 12.44 billion bushels and valued at an estimated \$5.15 to \$5.65 per bushel (USDA-NASS, 2012a). Corn is the most widely cultivated feed grain in the United States, accounting for approximately 96% of total value and production of feed grains (USDA-ERS, 2012). In addition to demand as feed grain, strong demand for ethanol production has resulted in higher corn prices and corresponding incentives to growers to increase corn acreage (USDA-ERS, 2012). In many cases, growers have increased corn acreage by adjusting corn plantings between corn, soybean, and other crops (USDA-ERS, 2012).

In 2011/2012, the United States produced approximately 36% of the total world supply of corn (USDA-OCE, 2012b). Corn is cultivated worldwide, including Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union states, including the Ukraine (USDA-OCE, 2011). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-OCE, 2012b). Approximately 15-20% of U.S. corn production is exported, with the volume of exports projected to decrease in the next several years because of increased competition from lower-priced South American supplies (USDA-OCE, 2012b). China is projected to become a net importer of corn to support its expanding livestock and industrial sectors (James, 2009; USDA-OCE, 2011, 2012a, 2012b). The increase in China’s imports are expected to account for one-third of the growth in world corn trade (USDA-OCE, 2012b). In addition to corn as grain, corn gluten feed is a major product in international trade in feed ingredients. Large volumes of U.S. corn gluten feed are exported to the EU (CRA, 2006).

Corn is the most widely cultivated feed grain, accounting for more than 95% of total value and production of feed grains (USDA-ERS, 2011b). Corn is grown in all 48 of the continental U.S.

states with production concentrated in the Corn Belt, loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-ERS, 2011a); (USDA-NASS, 2010). Iowa and Illinois, the two top corn producing states, typically account for slightly more than one-third of the total U.S. crop (USDA-ERS, 2011b). In the U.S. for the 2012 production year, corn was cultivated on over 96 million acres, a 5% increase in corn acreage from 2011 (USDA-NASS, 2012b). Within the 2010 acreage, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area (USDA-NASS, 2012c). Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated \$5.18 per bushel in 2010 and \$6.20 in 2011 (USDA-NASS, 2012b), (USDA-NASS, 2012e). GE herbicide-resistant corn comprised approximately 21% of the total corn acreage in the U.S.; insect-resistant varieties comprised 15% of the acreage, and stacked varieties comprising 52% of the total corn acreage (USDA-NASS, 2012b). The costs for GE corn seed are higher than that for conventional seed. Growers pay a premium for GE seed, with growers in 2008 paying as much as 50% more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010).

EPA . Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt. In the U.S. for the 2012 production year, corn was cultivated on over 96 million acres, a 5% increase in corn acreage from 2011 (USDA-NASS, 2012b). Within the 2010 acreage, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area (USDA-NASS, 2012c). Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated \$5.18 per bushel in 2010 and \$6.20 in 2011 (USDA-NASS, 2012b), (USDA-NASS, 2012e). GE herbicide-resistant corn comprised approximately 21% of the total corn acreage in the U.S., insect-resistant varieties comprised 15% of the acreage, and stacked varieties comprising 52% of the total corn acreage (USDA-NASS, 2012b). The costs for GE corn seed are higher than that for conventional seed. Growers pay a premium for GE seed, with growers in 2008 paying as much as 50% more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010).

USA-registered insecticides are currently being used on almost all of the corn acreage in the U.S. (USDA-APHIS, 2012a). Approximately 88% of corn fields were planted with transgenic corn in 2011 (USDA-NASS, 2011). Introduction of herbicide-resistant corn varieties, in particular glufosinate-resistant corn, has not significantly affected corn acreage managed with total herbicide application. A determination of nonregulated status of 4114 Maize is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE corn cultivation. The availability of 4114 Maize will not change cultivation areas for corn production in the U.S. and there are no anticipated changes to the availability of GE and non-GE corn varieties on the market.

Results of the agronomic and morphologic assessments conducted by Pioneer indicate that the introduced herbicide resistance trait does not confer any competitive advantage in terms of weediness (USDA-APHIS, 2012b). Pioneer asserts that 4114 Maize will be a replacement product for other varieties of corn currently cultivated, so it will not be expected increase corn acreage (Pioneer, 2011). The glufosinate-resistance trait, already in commercial use for fifteen

years, is not expected to extend the range of cultivation for 4114 Maize outside of existing cultivation areas (Pioneer, 2011).

## **Intensity**

Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

### *1. Impacts that may be both beneficial and adverse.*

In the past 30 years, the public's consumption of corn-based products has more than doubled. Per capita consumption of corn products rose from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners increased from 35.3 pounds annually per capita to 69.2 pounds during that period (USCB, 2011). As of 2012, 88% of the corn cultivated is GE (USDA-NASS, 2012b). Public health concerns associated with the use of GE corn, such as 4114 Maize, and GE-corn products focus primarily on human and animal (livestock) consumption of GE food and feed commodities. A determination of nonregulated status of 4114 Maize will have no significant environmental impact in relation to the availability of GE, conventional, and organic corn varieties.

As discussed in Chapter 4 of the EA, a determination of nonregulated status of 4114 Maize is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE-corn cultivation. The availability of 4114 Maize will not change the cultivation areas for corn production in the U.S. and there are no anticipated changes in the availability of GE and non-GE-corn varieties on the market. A determination of nonregulated status of 4114 Maize could add another GE corn variety to the conventional corn market and is not expected to change the market demands for GE-corn or corn produced using organic methods. GE and organic corn are planted on about 88% and 0.2% of corn acreage, respectively (USDA-ERS, 2010a). As of 2008, the most recent year for which data are available, approximately 168,000 acres of certified organic corn were grown in the U.S. Based on the data provided by Pioneer for 4114 Maize (Pioneer, 2011), APHIS has concluded that the availability of 4114 Maize would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE corn seed production (Pioneer, 2011). A determination of nonregulated status of 4114 Maize will not affect seed production practices, nor current production practices.

### *2. The degree to which the proposed action affects public health or safety.*

Non-GE-corn varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for human food or animal feed safety prior to release into the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. As a GE product, however, food and feed derived from 4114 Maize must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release into the market. Although a voluntary process, thus far all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA.

As part of a consultation, a developer who intends to commercialize a GE food meets with an FDA representative to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the GE food. This is followed by submission of a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; 3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require.

Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Pioneer has provided the FDA with information on the identity, function, and characterization of the genes for 4114 Maize, including expression of the gene products. The FDA completed its Biotechnology Consultation on March 25, 2013.

A determination of nonregulated status of 4114 Maize would have no significant impacts on human or animal health. 4114 Maize is compositionally similar to currently available corn on the market. Based on the FDA's consultation, laboratory data and scientific literature provided by Pioneer (Pioneer, 2011), APHIS has concluded that 4114 Maize would have no significant impacts on human or animal health.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of 4114 Maize. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of 4114 Maize. The product will be deployed on agricultural land currently suitable for production of corn, will replace existing varieties, and is not expected to increase the acreage of corn production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to 4114 Maize including the use of EPA-registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of 4114 Maize, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to corn production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The effects on the quality of the human environment from a determination of nonregulated status of 4114 Maize are not highly controversial. Although there is some opposition to a determination of nonregulated status of 4114 Maize, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment.

As discussed in Chapter 4 of the EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those acres devoted to GE-corn cultivation. The availability of 4114 Maize will not change cultivation areas for corn production in the U.S., and there are no anticipated changes to the availability of GE- and non-GE-corn varieties on the market.

A determination of nonregulated status of 4114 Maize could add another GE corn variety to the conventional corn market and is not expected to change the market demands for GE corn or corn produced using organic methods.

Pioneer 4114 Maize is currently registered by the EPA for breeding and seed-increase activities. A determination of nonregulated status of 4114 Maize will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application use/volunteer control. Management practices and seed standards for production of certified corn seed would not change.

The effect of 4114 Maize on wildlife or biodiversity is not different than that of other glufosinate-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing a determination of nonregulated status of 4114 Maize. No new issues, alternatives or new information were identified in any of the comments received by APHIS. APHIS has addressed substantive comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

*5. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

Based on the analysis documented in the EA, the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks to the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of 4114 Maize is not expected to directly cause an increase in agricultural acreage in general, or acreage devoted exclusively to GE-corn cultivation.

A determination of nonregulated status of 4114 Maize will not result in changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified corn seed would not change. The effect of 4114 Maize on wildlife or biodiversity is no different than that from other glufosinate-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well-established management

practices, production controls, and production practices (GE, conventional, and organic) are currently being used in corn production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional corn with GE and non-GE varieties, 4114 Maize, or by organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural corn production.

GE corn is currently planted on the majority (88% in 2010) of U.S. corn acreage (USDA-NASS, 2012b). Based on historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of 4114 Maize. Given the extensive experience that APHIS, stakeholders, and growers have extensive experience with GE-corn products that express *Bt* and PAT proteins, so the possible effects to the human environment from the release of an additional GE-corn product are already well-known and understood. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

A determination of nonregulated status for 4114 Maize would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340.

Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as 4114 Maize. When a petition for nonregulated status is submitted, APHIS must make a determination about plant pest risks associated with a GE organism. If it is unlikely to pose a plant pest risk then it is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340 regulations. These have been promulgated pursuant to authority granted APHIS by the PPA, as amended (7 United States Code (U.S.C.) 7701-7772), to regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products.

A GE organism is no longer subject to the plant pest provisions of the PPA or the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely

to pose a plant pest risk, so is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c) (4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism.

*7. Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on corn management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of 4114 Maize, APHIS would no longer have regulatory authority over this corn. In the event of a determination of nonregulated status of 4114 Maize, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of 4114 Maize when added to past, present, and reasonably foreseeable future actions.

*8. The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*

A determination of nonregulated status of 4114 Maize will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request. Tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of 4114 Maize would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of 4114 Maize. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of 4114 Maize is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act (NHPA). In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the use and enjoyment of a historic property when common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. An intrinsic mitigating factor is that the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the

audible qualities of such sites to their original condition with no further adverse effects. These cultivation practices also are already being conducted throughout the corn production regions. The cultivation of 4114 Maize does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

As described in Chapter 4 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of 4114 Maize on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of 4114 Maize, APHIS has determined that a determination of nonregulated status of 4114 Maize would have no effect on Federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

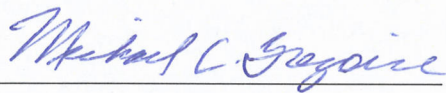
10. *Whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment.*

The proposed action would be in compliance with all Federal, State, and local laws. Because the agency has concluded that 4114 Maize is unlikely to pose a plant pest risk, a determination of nonregulated status of 4114 Maize is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

## NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that 4114 Maize is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of GE organisms consistent with the plant pest provisions of the PPA.

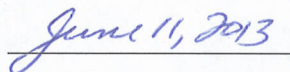
As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with 4114 Maize, the continued regulated status of 4114 Maize would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of 4114 Maize will not have any significant environmental effects.



Michael C. Gregoire

Deputy Administrator

Biotechnology Regulatory Services



Date

## REFERENCES

- AOSCA. (2010) General IP Protocols Standards. The Association of Official Seed Certifying Agencies. Retrieved November 8, 2010 from <http://www.identitypreserved.com/handbook/aosca-general.htm>.
- CRA (2006). Corn Wet Milled Feed Products. Submitted by Registration Manager. Corn Refiners Association (See Table
- Hammond BG and Jez JM. (2011) Impact of food processing on the safety assessment for proteins introduced into biotechnology-derived soybean and corn crops. *Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association*, 49(4), 711-721.
- James C. (2009) Global Status of Commercialized Biotech/GM Crops: 2009. Ithica, NY: ISAAA. Retrieved from
- NRC. (2010) *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*. Washington, DC: National Academies Press.
- OSTP (2001). Case Study No. III. Herbicide-tolerant Soybean. Submitted by Registration Manager. (See Table
- Pioneer. (2011) Petition for the Determination of Nonregulated Status for Insect-Resistant and Herbicide-Tolerant 4114 Maize. Submitted by N. Weber, Registration Manager. Johnston, IA: Pioneer Hi-Bred International, Inc. Retrieved 9 November 2011, from
- US-EPA. (2008). Glufosinate Summary Document, Registration Review: Initial Docket, March 2008, Case #7224. Last accessed from
- US-EPA. (2010) Glufosinate Ammonium; Tolerances for Residues, 40 CFR §180.473
- US-EPA. (2011a) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). U.S. Environmental Protection Agency. Retrieved January 20 2012, from <http://www.epa.gov/agriculture/lfra.html>.
- US-EPA. (2011b) Glufosinate Ammonium Case. United States Environmental Protection Agency. Retrieved from [http://www.epa.gov/oppsrrd1/registration\\_review/glufosinate\\_ammonium/](http://www.epa.gov/oppsrrd1/registration_review/glufosinate_ammonium/).
- US-EPA. (2011c) Pesticides: Registration Review. Retrieved June 30, 2011 from [http://www.epa.gov/oppsrrd1/registration\\_review/](http://www.epa.gov/oppsrrd1/registration_review/).
- US-EPA. (2011d) Summary of the Federal Food, Drug, and Cosmetic Act (FFDCA). U.S. Environmental Protection Agency. Retrieved January 20, 2012 from <http://www.epa.gov/regulations/laws/ffdca.html>.
- US-FDA. (2011). Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use. Last accessed from <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096156.htm>
- USCB. (2011) Table 213. Per Capita Consumption of Major food Commodities: 1980 to 2008. Retrieved May 18, 2011 from <http://www.census.gov/compendia/statab/2011/tables/11s0213.pdf>.
- USDA-APHIS. (2012a) Plant Pest Risk Assessment for Genective Event VCO-Ø1981-5 Corn. Riverdale, MD: US Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from

- USDA-APHIS. (2012b) Plant Pest Risk Assessment for Pioneer 4114 Maize. Riverdale, MD: US Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from
- USDA-ERS. (2010a) Adoption of Genetically Engineered Crops in the U.S.: Corn Varieties. Retrieved April 4, 2011 from <http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm>.
- USDA-ERS. (2011a) Corn: Background. Retrieved March 31, 2011 from <http://www.ers.usda.gov/Briefing/Corn/background.htm>.
- USDA-ERS. (2011b) Feed Outlook, FDS-11a, January 14, 2011. Retrieved January 14, 2011, from <http://usda.mannlib.cornell.edu/usda/ers/FDS/2010s/2011/FDS-01-14-2011.pdf>.
- USDA-ERS. (2012) Corn: Background. Retrieved 19 October, 2012 from <http://www.ers.usda.gov/topics/crops/corn/background.aspx>.
- USDA-NASS. (2010) Acreage. Retrieved March 30, 2011 from <http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2010.pdf>.
- USDA-NASS. (2011) Agricultural Chemical Usage 2010 Corn, Upland Cotton, Fall Potatoes. Retrieved May 25, 2011, from [http://www.nass.usda.gov/Surveys/Guide\\_to\\_NASS\\_Surveys/Chemical\\_Use/FieldCropChemicalUseFactSheet06.09.11.pdf](http://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Chemical_Use/FieldCropChemicalUseFactSheet06.09.11.pdf).
- USDA-NASS. (2012a) Acreage. ISSN: 1949-1522. USDA, National Agricultural Statistics Service, Agricultural Statistics Board. Retrieved from <http://usda01.library.cornell.edu/usda/current/Acre/Acre-06-29-2012.pdf>.
- USDA-NASS (2012b). Acreage. Submitted by Registration Manager. National Agricultural Statistics Service, Agricultural Statistics Board, USDA (See Table <http://www.usda.gov/nass/PUBS/TODAYRPT/acrg0612.pdf>).
- USDA-NASS. (2012c) Crop Production 2011 Summary. National Agricultural Statistics Service. Retrieved 2012 June, from <http://usda01.library.cornell.edu/usda/current/CropProdSu/CropProdSu-01-12-2012.pdf>.
- USDA-NASS. (2012d) Crop Production, 2011 Summary USDA, National Agricultural Statistics Service. Retrieved from
- USDA-NASS. (2012e) Crop Values 2011 Summary. U.S. Department of Agriculture–National Agricultural Statistics Service. Retrieved February, 2012 from <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1050>.
- USDA-OCE. (2011) World Agricultural Supply and Demand Estimates. Office of the Chief Economist, Agricultural Marketing Service, Farm Service Agency, Economic Research Service, Foreign Agricultural Service. Retrieved from <http://usda.mannlib.cornell.edu/usda/waob/wasde//2010s/2011/wasde-03-10-2011.pdf>.
- USDA-OCE. (2012a) USDA Agricultural Projections to 2021. Long-term Projections Report OCE-2012-1. Office of the Chief Economist, World Agricultural Outlook Board, U.S. Department of Agriculture. Prepared by the Interagency Agricultural Projections Committee. Retrieved from
- USDA-OCE. (2012b) World Agricultural Supply and Demand Estimates. USDA - Office of the Chief Economist, Agricultural Marketing Service, Farm Service Agency, Economic Research Service, and Foreign Agricultural Service. Retrieved 10 August 2012, from



## Response to Public Comments on Pioneer DP-04114-3 Maize

On February 27, 2013, APHIS published a notice in the *Federal Register* (78 FR 13312-13313, Docket no. APHIS-2012-0026) announcing the availability of the Pioneer petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before April 29, 2013. The docket folder containing the comments can be located<sup>3</sup> at <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dc=PS;D=APHIS-2012-0026>

APHIS received a total of 12 submissions to the docket from various individuals and groups on the DP-004114-3 corn petition (hereafter referred to as 4114 Maize), PPRA, and draft EA. Most comments expressed opposition to the development of GE foods and/or 4114 Maize. Public comments included individual submissions and form letters. Some of these cited issues from both the peer-reviewed and non-peer-reviewed literature. One public comment supported a determination of nonregulated status of 4114 MaizeCorn. It was submitted by a corn grower association. It cited several reasons that indicate potential benefits of 4114 Maize, and noted that 4114 Maize will provide an additional variety of corn to combat persistent, yield-reducing pests in production agriculture.

Eleven public comments expressed opposition to a determination of nonregulated status of 4114 Maize. One of these was a cover letter with 561 identical form letters attached to it. Five of the opposing public comments contained only references, with no other information. These were intended to support a comment submitted by a nongovernmental organization (NGO).

Many of the public comments expressed an opinion(s) that could be categorized in one or more of the following: general opposition to genetically modified organisms (GMOs) or GE crops and the domestic regulatory process surrounding GE plants; perceived negative effects on public and animal health, biodiversity, and the environment; lack of consideration for organic production systems; the public right to choose non-GE containing food products.

A number of comments challenged the adequacy of APHIS' preparation and analysis in the Draft Environmental Assessment (DEA). These commenters expressed concern with regard to the scientific basis, structure, scope and analysis of APHIS' NEPA analysis as it relates to the Plant Pest Risk Assessment process. Other comments expressed concern with regard to the substance of APHIS' NEPA analysis and APHIS' analysis of impacts and reasonably foreseeable harm and consideration of alternatives. Several comments urged the agency to prepare a full

---

<sup>3</sup> Hyperlink cannot be directly opened. The hyperlink must be pasted in web browser address bar to be functional.

Environmental Impact Statement (EIS) and to consult with the U.S. Fish and Wildlife Service under section 7 of the Endangered Species Act (ESA).

However, the majority of these public comments did not explain or identify elements in the 4114 Maize PPRA or EA that were perceived to be inadequate or provide any supporting evidence for their claims. Several specific issues related to the 4114 Corn EA were, however, identified from the collective pool of public comments and form letter submissions. These were organized into categories and addressed below.

### **Issue 1**

A comment submitted on the closing date of the docket stated that because multiple dockets for petitions were posted for the same 60-day period, the public was not afforded enough time to review all documents. The commenter requested an extension of the comment period.

### **APHIS Response**

APHIS posted several dockets on the same day. Four petitions were posted seeking comment on each petition. This included an NOI to prepare an EIS for the action associated with one of those petitions. APHIS also published the draft EA and PPRA for this docket as well as a second docket related to a petition request. In addition APHIS published two final determinations. APHIS deemed the 60-day comment period sufficient opportunity for the public to provide meaningful comment on this EA. Following the comment period, the Agency thoroughly reviewed the comments and will have carefully considered other inputs as it prepared APHIS' final plant pest risk assessment, environmental assessment, FONSI and regulatory determination in response to this petition for nonregulated status of 4114 Maize.

### **Issue 2**

A commenter suggested that APHIS examine the composition of 4114 Maize after being sprayed with glufosinate, citing findings by Reddy et al. (Reddy et al., 2011), that levels of several chemical components were altered following spraying of glufosinate-resistant soybean with glufosinate. These components included two fatty acids, protein content, and oil content. The commenter stated that:

(Reddy et al., 2011) Reddy et al. speculate in very general terms that "glufosinate may alter carbon metabolism," citing similar effects exerted by glyphosate; that increased protein could be a stress response of the soybean to glufosinate treatment; and that the increase in oleic acid and decline in linolenic acid "could be due to indirect physiological disturbances that affect fatty acid desaturases or to an alteration in carbon metabolism." These general speculations, however, are little more than restatements of the observed effects in more technical terms. The issue is not the safety implications of the detected changes; the changes in oleic and linolenic acid levels obviously do not pose risks. The point is that these few significant changes that happened to be detected through very limited testing almost certainly point to a host of other unknown compositional effects, some of which could have serious adverse implications.

### **APHIS Response**

In its petition, Pioneer (Pioneer, 2011b) presents comprehensive results of compositional analyses of multiple replicates of field trial plantings of 4114 Maize, and compared them with several other corn lines. Their analysis used the OECD (OECD, 2002) publication on suggested parameters for chemical composition of corn. These values include percent moisture, total fat, protein, total dietary fiber, mineral and vitamin levels, amino acid composition, fatty acid composition, anti-nutrients and allergens. Pioneer presents a compositional analysis of 4114 Maize, which was reviewed by APHIS, which in turn, verified that levels of compounds in 4114 Maize were consistent with levels reported by OECD (OECD, 2002; Pioneer, 2011b). These corn plants were not treated with glufosinate prior to testing, all other applicable requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) (Pioneer, 2011b).

The commenter states the Reddy paper (Reddy et al., 2011) discussion of implications for glufosinate metabolism is speculative, and that suggestions that the changes in oleic acid and linolenic acid “do not pose safety risks”. The commenter’s statement that these results suggest other “significant changes” with possible “serious adverse implications” is also speculative. The commenter does not provide an adequate rationale to support these statements.

With respect to the chemical composition changes of glufosinate-resistant soybeans found by Reddy (Reddy et al., 2011), these changes include an increase in protein content and oleic acid percent, and a decrease in oil content, and linolenic acid percent. However, when compared with the crop composition database values in the International Life Sciences Institute (ILSI) ([www.cropcomposition.org](http://www.cropcomposition.org)), the treatment value for linolenic acid is found to be within the normal range for soybean seed. The value for oleic acid is slightly higher than the range given for soybean seed in the ILSI database, but much lower than oleic acid ranges published in the environmental report for Pioneer High Oleic Acid 304523 soybean (USDA-APHIS, 2010), which has been deregulated. With exception of the intended changes in fatty acid composition of the seed, Pioneer High Oleic Acid 304523 soybean was shown to be similar to conventional soybean varieties in agronomic, ecological and compositional characteristics and have the same levels of resistance to insects and diseases. Quantitative values for protein and oil content from the Reddy paper are expressed in different units from those in the ILSI database, so cannot be compared.

APHIS acknowledges that when corn is sprayed with glufosinate, there may be similar changes in some chemical components as in soybean. However, APHIS has not identified any studies that specifically examine the changes in chemical composition in corn that is sprayed with glufosinate. A study related to the metabolism of glufosinate in glufosinate resistant plants indicates that the main metabolites are similar in corn and canola (Ruhland et al., 2004). Since it is likely that the changes in composition seen in soybean are related to the metabolism of glufosinate, and glufosinate metabolism is similar in a monocot (corn) and a dicot (canola) (Ruhland et al., 2004), it is also likely that compositional changes in corn could be similar to those seen in soy. As the commenter indicates, the changes “do not pose safety risks.”

### **Issue 3**

Three commenters asserted that Pioneer has not been successful in obtaining sufficient authorizations to import 4114 Maize in other countries. They stated that failure to obtain the

authorizations in key markets within the world would create a risk of significant economic losses to U.S. grain and oilseed producers and markets.

### **APHIS Response**

Pioneer has applied to the following countries for cultivation approval or importation of 4114 Maize: Canada, Mexico, Japan, South Korea, Taiwan, China, Colombia, and the EU. According to the company, prior to commercialization of 4114 Maize, Pioneer will meet all applicable regulatory requirements in key countries that are likely to import 4114 Maize (Hyten, 2013). When international acceptance of a specific event has not been attained, US elevators and grain buyers may either refuse to purchase the grain, or may require that it be diverted to elevators that are solely designated as sources for domestic grain sale (Anonymous, 2011).

### **Issue 4**

A commenter asserted that insecticide use is increasing as a result of the use of GE crops, and that APHIS did not consider insecticide-treated seed corn in its analysis of this issue. The commenter also stated that APHIS is incorrect in its assumption that *Bt* corn will lead to reduced insecticide use.

### **APHIS Response**

Most seed corn is treated with insecticide in order to combat corn pests which attack the seed. As discussed in the EA, and presented graphically in Figure 2-1, the percentage of corn acreage planted with seed that was treated with insecticides has risen from about 20% in 2004, to about 90% in 2009-2011. Chemical insecticides commonly used in corn seed treatment to control of seed corn insect pests such as flea beetles, cutworm larvae, seed corn maggots, white grubs, and wireworms, include imidacloprid, clothianidin, fipronil, permethrin, and thiamethoxam (Whitworth et al., 2013).

Insecticidal seed treatment is not equivalent to post-planting insecticidal treatment, which carries a small risk of environmental exposure from pesticide drift. As mentioned in the EA, contrary to the comment, Benbrook (Benbrook, 2012) and Brookes and Barfoot (Brookes and Barfoot, 2010) report that there has been a decrease in the use of soil or foliar insecticides in the last several years, partially due to the use of *Bt*-incorporated crops.

*Bt* is a microbial insecticide, and its expression in plants can reduce the need for foliar application of insecticides. *Bt* is considered safe to humans and other vertebrates, because of its high selectivity to a few groups of insects (Then, 2010). With greater selectivity afforded by *Bt* corn, the grower can avoid use of broad-spectrum insecticides (Brookes and Barfoot, 2010), allowing growers to decrease insecticidal applications (Benbrook, 2012; Brookes and Barfoot, 2010).

APHIS has reviewed insecticide use in section 2.2.2.3, Agronomic Inputs, and disagrees with the commenter's statement that insecticide use is increasing rather than decreasing, allowing growers to decrease insecticidal applications (Benbrook, 2012; Brookes and Barfoot, 2010).

APHIS has reviewed insecticide use in section 2.2.2.3, Agronomic Inputs, and disagrees with the commenter's statement that insecticide use is increasing rather than decreasing.

## **Issue 5**

A commenter stated that "APHIS needs to explain how herbicide-resistant crops, particularly herbicide-resistant corn can decrease herbicide use by the amount suggested by Brookes and Barfoot (Brookes and Barfoot, 2012), when herbicide use has increased substantially over the years of its adoption."

The commenter also stated that the "APHIS' treatment of pesticide use is in blatant violation of Executive Order 13563, which demands with respect to emerging technologies that: 'Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency.' APHIS' treatment of pesticide use in the plant pest risk assessment and draft EA is in blatant violation of the Plant Protection Act."

Additionally, the commenter also stated that there were some factual errors related to herbicide use in the EA, such as the listing of an herbicide not labeled for use on corn (e.g., fomasafen) or the inverse relationship between metachlor and glyphosate use.

## **APHIS Response**

GE crop adoption is not responsible for all of the increase in agricultural herbicide use. Moreover, products with the same phenotypes as those contained in 4114 Maize are already nonregulated and available on the market.

As stated throughout the EA, the glufosinate-resistant trait in 4114 Maize is already present in currently-available corn hybrid varieties (e.g., 1507, 59122, and 1507 x 59122 corn). Because this identical glufosinate-resistant trait is already established in the U.S. corn market, and 4114 Maize itself does not require any changes in glufosinate application, there is no reason to believe that a determination of nonregulated status of 4114 Maize will promote changes in current herbicide use practices. The commenter does not provide any basis by which a determination of 4114 Maize itself will affect current herbicide use patterns.

APHIS disagrees that it needs to explain the commenters interpretation of a particular reference. APHIS acknowledges differing interpretations of data related to GE corn adoption and herbicide use in sections 2.2.2.3 and 4.2.2 of the EA (e.g., (Benbrook, 2012) and (Brookes et al., 2012)). APHIS recognizes that different reports base their analysis on differing interpretations of available data. The action on this petition will not change the overall trends associated with herbicide use in agriculture or the contribution of GE crops generally to that herbicide use. Global trends in GE corn adoption and management practices are outside the scope of this EA. This EA was prepared to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of 4114 Maize. These potential environmental impacts on the human environment are discussed in Sections 2, 4, and 5, 6, and 7 of the EA. As discussed in the EA, 4114 Maize is phenotypically identical to corn that is currently commercially available. The analysis in the EA indicates that the area planted to

corn and the management practices associated with corn will not change when compared to the no action alternative. APHIS disagrees that it needs to expand the scope of this EA to include issues related to general adoption herbicide-resistant corn varieties and herbicide use. Herbicide use is regulated by the EPA, not the USDA.

With respect to the factual errors related to herbicide use in the EA, APHIS recognizes these errors and has revised Sections 2.2.3, Agronomic Inputs, and 4.4.2.1, Plant Communities, of the EA.

APHIS disagrees with the suggestion that it has failed to base its treatment of pesticide use in the DEA on sound science in accordance with the requirements of Executive Order 13563. APHIS used sound science to inform its regulatory decision regarding plant pest risk of 4114 Maize, and has determined that 4114 Maize is not a plant pest risk. APHIS carefully reviewed the information provided by the petitioner and others and considered all other relevant information sufficient to make the determination on whether to deregulate the 4114 Maize. In its NEPA analysis, APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for Pioneer 4114 Maize is adequate and sufficient. The EA follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA. APHIS considered opposing views, and reviewed the information provided by those who supported or opposed 4114 Maize deregulation, APHIS analyzed the socioeconomic impacts of each of the alternatives evaluated.

## **Issue 6**

A commenter stated that there is no causal relationship between the use of GE herbicide-resistant corn and adoption of conservation tillage in corn production systems, and that this observation “suggest strongly that 4114 Maize hybrids, will not, as APHIS inconsistently claims, support continued use of conservation tillage systems in corn.” The commenter also disagreed with APHIS’ statement in the DEA that conservation tillage in corn has increased considerably since 2001. Another comment expressed the view that APHIS has a duty to fully assess the foreseeable impact upon tillage, as the correlation between conservation tillage and GE corn is weak and complicated by foreseeable volunteer corn problems. The commenter suggested that APHIS itself has questioned whether herbicide-resistant cropping systems have in effect increased conservation tillage and had failed to consider the negative impact on conservation tillage by reasonably foreseeable development of resistant weeds and volunteers. One comment also stated that APHIS incorrectly uses the term “reduced till.”

## **APHIS Response**

APHIS acknowledges that there is no strong direct relationship between GE herbicide-resistant corn adoption and the use of conservation tillage in corn production (e.g., section 2.2.2.1 and 4.2.2 of the DEA); interestingly, the commenter also acknowledged that APHIS recognized this absence of a relationship (e.g., “APHIS concedes that use of conservation tillage practices in corn is not attributable to the adoption of herbicide-resistant corn varieties”). However, APHIS disagrees with the commenter’s statement that the DEA “suggest strongly that 4114 Maize hybrids, will not, as APHIS inconsistently claims, support continued use of conservation tillage

systems in corn.” As stated in the DEA at section 4.2.2.2, “Under the Preferred Alternative, current trends and practices related to tillage . . . are unlikely to be substantially different than that which is occurring under the No Action Alternative in Subsection 4.2.2.1 – Agronomic Practices.” As stated throughout the DEA, the glufosinate-resistant trait in 4114 Maize is already present in currently-available corn hybrid varieties (e.g., 1507, 59122, and 1507 x 59122 corn). Because this identical glufosinate-resistant trait is already established in the U.S. corn market, and 4114 Maize itself does not require any changes in glufosinate application, there is no reason to suspect that any change would occur in herbicide use or conservation tillage practices following a determination of nonregulated status of 4114 Maize. APHIS agrees with the commenter’s statement that APHIS incorrectly included reduced tillage in the types of conservation tillage. APHIS corrected the EA. The terms conservation tillage and reduced tillage are correctly defined in section 2.2.2.1 of the EA.

## **Issue 7**

One commenter stated that a determination of nonregulated status of 4114 Maize will reduce corn seed options for farmers, thus reducing the choice of affordable seed options to farmers (e.g., “By accelerating the introduction of highly-stacked varieties and displacing its predecessor 1507 and 59122 lines . . . it will reduce the choice of more affordable seed options” and “Contrary to APHIS (EA at 109), once 4114 Maize replaces 1507 x 59122, Dupont-Pioneer will have little reason to continue offering either 1507 or 59122.”). The commenter also stated that APHIS is incorrect in stating that 4114 Maize will possess a lower price relative to other corn hybrids, such as 1507 x 59122 corn.

Another commenter expressed concerns with regard to an issue, characterized as “seed market concentration,” and the effects on scientific research. The commenter stated the view that such concentration was affecting the ability of independent researchers to fully investigate patented crop performance and that the integrity of such research was being undermined by the companies exercise of its right to review and approve all publications. In the view of the commenter, this has had a deterrent effect upon needed research and development in the area. The commenter maintained that increasingly, as the seed supply is becoming patented and owner-concentrated in multinational corporations, that grower choice becomes limited and costs increase, and given such seed market concentration, APHIS must analyze the socio-economic cost of the loss of conventional seed as the increased cost of GE seed is ultimately reflected in the cost of food to the public at large.

## **APHIS Response**

APHIS disagrees that a determination of nonregulated status of 4114 Maize will reduce corn seed options for farmers, thus reducing the choice of affordable seed options to farmers. The commenter bases this assertion that the determination of nonregulated status of 4114 Maize will lead to the retirement of corn varieties containing the traits in 4114 Maize, such as 1507, 59122, and 1507 x 59122 (e.g., As APHIS asserts repeatedly throughout the draft EA, “4114 will be incorporated in hybrids designed to substitute for or replace current varieties that incorporate 1507 and/or 59122 . . . this means that Dupont-Pioneer will retire these replaced predecessor

lines.”) The comment does not provide any basis for this assertion. APHIS contacted the developer and received the follow response:

“Although Pioneer intends to gradually substitute 4114 for 1507 x 59122 in many Maize hybrid offerings, for the foreseeable future Pioneer will also continue to sell Maize hybrids that contain 1507, 59122, or 1507 x 59122.”

The developer intends to continue selling 1507, 59122, or 1507 x 59122 corn hybrids following a determination of nonregulated status for 4114 Maize. Consequently, a reduction in farmer seed options is not anticipated because 1507, 59122, and 1507 x 59122 corn hybrids will continue to be offered on the market following a determination of nonregulated status of 4114 Maize.

APHIS agrees with the commenter’s statement that 4114 Maize will not possess a lower price relative to other corn hybrids and has corrected this in the final EA and PPRA.

The adoption of 4114 Maize should not change the base line dynamics or market forces within the corn seed industry or the way that corn is tested, researched, developed or marketed in the United States. Corn varieties are developed at considerable cost, have value as intellectual property and as such, patent holders may seek legal means to preserve, protect and limit access to such intellectual property at their discretion. Such rights are subject to the rule of law, the baseline relationship of patent holders to others seeking to use intellectual property, as administrated by the U.S. Patent and Trade Office, and this would not be changed by the deregulation of 4114 Maize. Therefore issues of the rights of others to do research are within the existing norm of patent law and as such generally outside the scope of the EA. The action on the petition to deregulate 4114 Maize will not effect that existing baseline as to what can or cannot be patented and rights individuals may have in regards to patented seed. It will not change how seed is marketed. Companies will continue making decisions to supply seed varieties based on factors such as available markets and potential returns.

## **Issue 8**

One commenter stated that a determination of nonregulated status of 4114 Maize will “facilitate more continuous corn and its adverse impacts.”

### **APHIS Response**

APHIS disagrees with the comment. As stated in the EA in Sections 2.2.1 and 4.2.1, corn acreage and continuous corn production is already increasing in the absence of 4114 Maize. This increase in U.S. corn acreage and continuous corn production is driven primarily by external market forces (e.g., corn grain pricing) and government policies (e.g., decrease in Conservation Reserve Program enrollment acreage and increased funding for Working Land Conservation Programs).

The commenter also acknowledged these factors as drivers for the increase of corn acreage in the United States (e.g., “Corn acreage has been increasing dramatically ... driven by high corn prices that are in turn stoked by demand for corn to make ethanol...” and “U.S. agricultural policies promotes corn like no other crop by means of billions of dollars in market-distorting subsidies

...”), while also acknowledging this discussion in the EA (e.g., As APHIS notes, “strong demand for corn to supply the rapidly growing ethanol industry has raised corn prices in recent years (EA at 10) ... This demand ... has made corn relatively more profitable than other crops ... farmers, who have responded by growing more corn.”).

The commenter asserted, but did not identify a specific reason why a determination of nonregulated status of 4114 Maize itself would lead to increased corn acreage or increased continuous corn production. As stated throughout the EA, current corn hybrid varieties on the U.S. market contain the traits in 4114 Maize (e.g., 1507 x 59122 corn), and 4114 Maize is phenotypically identical to that corn hybrid variety. The commenter does not explicitly identify a reason why 4114 Maize would increase corn acreage or increase continuous corn production compared to these current and phenotypically similar corn hybrid varieties. Furthermore, the commenter does not explain the assertion that 4114 Maize itself will lead to altered rotational practices, which in turn can also affect a grower’s decision to plant continuous corn.

Thus, based on the observation that market forces and government policies are the primary drivers of increasing corn acreage and continuous corn production, and the absence of any rationale as to why 4114 Maize itself will increase corn acreage or continuous corn production compared to currently available corn varieties, APHIS disagrees with the comment and its speculations on corn management practice. There is no reason that a determination of nonregulated status of 4114 Maize would lead to an increase in corn acreage or an increase in continuous corn production in the United States when compared to the no action alternative.

## **Issue 9**

One commenter stated that a determination of nonregulated status of 4114 Maize will “make more use of glufosinate-resistance in corn by applying more of the herbicides as GR weeds worsen in the years to come,” leading to “. . . increase in glufosinate use [that] will impact non-target . . . .” Non-target plants include plants, animals, insects, and microbial organisms. The commenter also stated that this increased use of glufosinate will adversely affect human health.

## **APHIS Response**

APHIS disagrees with the commenter’s assertions. The commenter’s statement on adverse impacts is based on the assumption that a determination of nonregulated status of 4114 Maize will increase corn glufosinate use to manage glyphosate-resistant weeds. Existing corn varieties are available that are phenotypically identical to 4114 Corn (e.g., 1507, 59122, and 1507 x 59122 corn). The commenter does not identify a reason why glufosinate use would be any different in 4114 Maize than in these existing glufosinate-resistant corn varieties, when compared to the no action alternative.

APHIS also disagrees that a determination of nonregulated status of 4114 Maize will lead to adverse impacts on non-target organisms and human health. Again this statement is based on the assumption that a determination of 4114 Maize will lead to increased glufosinate use. As discussed above, there is no reason to suspect that an increase in glufosinate use will occur solely as a result of a determination of nonregulated status of 4114 Maize, or that glufosinate use will

differ between 4114 Maize and current corn hybrids that are already resistant to glufosinate. Therefore, a determination of nonregulated status of 4114 Maize itself is unlikely to adversely affect non-target organisms and human health. As mentioned in the DEA, EPA is directly responsible for herbicide registration in the United States. As a result of this authority, EPA examines effects to non-target organisms and human health pursuant to its herbicide registration and reregistration program<sup>4</sup>. EPA is currently evaluating glufosinate for reregistration<sup>5</sup>. If EPA determines that glufosinate poses any unreasonable risks to non-target organisms or human health, the agency will take appropriate measures to prevent unreasonable risks to non-target organisms or human health.

## **Issue 10**

A commenter stated that APHIS' analysis of 4114 Maize's impact on threatened and endangered species is insufficient because recent EPA environmental fate and ecological risk assessments for the registration review of glufosinate indicate that labeled uses are likely to exceed levels of concern for listed species; therefore, APHIS must initiate consultations with the appropriate Federal agencies. The commenter also expressed concern for listed plants that may be near fields of 4114 Maize because of increased risk from exposure to herbicides as a result of drift, runoff, accidental overspraying, and impacts of recently sprayed plant parts on soil.

## **APHIS Response**

Section 7 of the Endangered Species Act requires Federal agencies to ensure that any action they authorize is not likely to jeopardize the continued existence of any threatened or endangered species or adversely modify designated critical habitat. It is the responsibility of the agency to assess the effects of the action and to consult with the FWS if the action "may affect" listed species or critical habitat. To do this, the agency obtains a list of species that may be found in the "action area." from the United States Fish and Wildlife Service and/or the National Marine Fisheries Service (USFWS/NMFS).

As required, APHIS considered the potential for effects from the proposed determination of nonregulated status for Pioneer 4114 Maize on federally listed threatened and endangered species and species proposed for listing as well as designated critical habitat and habitat proposed for designation. APHIS obtained a list of species from USFWS/NMFS. After analyzing the potential for any effect, APHIS reached a determination that the determination of nonregulated status for the Pioneer 4114 Maize will have no effect on federally listed threatened or endangered species or species proposed for listing, and no effect on designated critical habitat or habitat proposed for designation. Therefore, consultation with the USFWS is not required.

---

<sup>4</sup> <http://www.epa.gov/pesticides/factsheets/registration.htm> ; Last accessed May, 2013

<sup>5</sup> <http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2008-0190> ; Last accessed May, 2013

Since preparation of the draft EA, EPA has prepared a preliminary environmental fate and ecological assessment for the registration review of glufosinate which reviewed the most recent environmental fate and effects data. The public comment period for this document closed on May 6, 2013. As the commenter pointed out, the findings of the assessment conclude that registered uses of glufosinate may result in risk to listed threatened and endangered species. However, it is not APHIS' responsibility to consult with the Services concerning the effects of registration and use of herbicides. APHIS presumes that EPA will consult with the Services, as appropriate, if in its final review, EPA determines that registration and subsequent use of glufosinate will affect listed species or critical habitat.

USDA-APHIS met with USFWS officials on June 15, 2011, to discuss whether USDA-APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and USDA-APHIS have agreed that it is not necessary for USDA-APHIS to perform an ESA effects analysis on herbicide use associated with GE crops because US-EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. USDA-APHIS has no statutory authority to authorize or regulate the use of glufosinate, or any other herbicide used by corn growers. Under USDA-APHIS' current Part 340 regulations, USDA-APHIS only has the authority to regulate Pioneer 4114 Maize or any GE organism as long as USDA-APHIS believes it may pose a plant pest risk. For GE organisms, USDA-APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

## **Issue 11**

A commenter stated that a determination of nonregulated status of 4114 Maize will lead to increased selection pressure for *Bt* resistance in corn rootworm, leading to higher frequencies of *Bt*-resistant corn rootworm populations.

## **APHIS Response**

APHIS disagrees that a determination of nonregulated status of 4114 Maize will lead to increased selection pressure for *Bt* resistance in corn rootworm, thus leading to higher frequencies of *Bt*-resistant corn rootworm populations. A determination of nonregulated status of 4114 Maize will not lead to an increase in continuous corn production or the elimination of corn hybrid varieties not containing a corn rootworm resistant trait (e.g., 1507 corn).

With regard to the presence of volunteer 4114 Maize increasing selection pressure for *Bt*-resistance in corn rootworm, the commenter did not provide any support for the assertion that a determination of nonregulated status of 4114 Maize, itself, will increase selection pressure for *Bt*-resistance in corn rootworm toxin. It is quite possible that 4114 Maize volunteers would also express lower levels of its Cry34Ab1/Cry35Ab1 toxin, presenting similar issues, especially when compared to existing corn hybrid varieties that already contain the identical corn rootworm-resistant trait. As mentioned throughout the EA, corn hybrid varieties already contain the same identical corn rootworm-resistant trait as 4114 Maize (e.g., 59122 and 1507 x 59122 corn). The commenter provided no evidence that 4114 Maize is any different than these existing corn hybrid

varieties with respect to selection pressure for *Bt*-resistance in corn rootworm, or that this difference in 4114 Maize will lead to increased selection pressure for *Bt*-resistance in corn rootworm.

Four populations of western corn rootworm in Iowa were found to have evolved resistance to CryBb1 corn (Gassmann et al., 2011). This resistance has been attributed to grower failure to implement the refuge component of insect resistance management (IRM). Widespread failure of control measures using *Bt* crops has not been observed, in part due to IRM strategies. IRM strategies generally include supplemental pesticide use and the planting of refuges (Tabashnik et al., 2008). In the case of *Bt* corn grown in the Corn Belt, refuge acreage is typically 5-20% of the cornfield area, depending on the product's requirements (US-EPA, 2010).

Resistance management strategies, which are mandated by US-EPA's terms of *Bt*-corn-product registrations (US-EPA, 2010) have been developed for all *Bt*-corn products to mitigate the risk of pest resistance and to implement additional measures if resistance occurs. As a condition of *Bt* registrations by US-EPA, registrants are required to develop IRM programs to delay the development of insect resistance to Cry proteins. Examples of the limitations and conditions currently implemented for the *Bt* proteins in corn can be found in the EPA document, *Terms and Conditions for Bt Corn Registrations* (US-EPA, 2010). As part of this program, growers of traditional *Bt*-corn products are required to plant a non-*Bt*-corn refuge (US-EPA, 2010). Such a refuge can consist of a field or a block or strip of non-*Bt* corn (US-EPA, 2010).

The US-EPA has also approved recently an integrated refuge strategy, named "refuge in a bag", where a small quantity of non-*Bt* seeds are blended with the *Bt* corn seed products and planted randomly within the field (Pioneer, 2012). Successful development and implementation of the refuge strategy requires an understanding of the genetic foundation of insect pest resistance. Incipient resistance to Cry proteins has been reported in target insect pests before being exposed to the Cry proteins (Mahon et al., 2012). This resistance trait is considered a recessive allele; susceptibility to the Cry protein is considered the dominant trait (Tabashnik and Gould, 2012). As a recessive trait, the frequency of expression of this trait is low in an unexposed population (Tabashnik and Gould, 2012). However, when the same population of target pests is exposed to the same Cry protein over several generations, the recessive resistance trait allows those individuals carrying that allele to survive and reproduce, conferring the resistance trait to their offspring as a greater percentage of the pest population (Tabashnik and Gould, 2012).

The refuge strategy provides non-*Bt* corn. The susceptible target insects (e.g., European corn borer and/or corn rootworms) can feed, mate and reproduce without exposure to the *Bt* corn and the Cry proteins, maintaining a genetic reservoir of susceptible target pests that express the dominant trait (Pioneer, 2012; US-EPA, 2010). (Pioneer, 2012; US-EPA, 2010). Future mating interactions with these susceptible insects (i.e., those that have not been exposed to *Bt* proteins) with those that have been exposed to the *Bt* proteins and survived based on the resistance allele will ensure that *Bt* resistance does not become the dominant allele in the population (Pioneer, 2012).

In summary, because a determination of nonregulated status, 4114 Maize will not lead to increased continuous corn production, elimination of corn hybrid varieties not containing a corn

rootworm resistant trait, or increased selection pressure for *Bt*-resistance in corn rootworm as a result of volunteer 4114 Maize. There is no reason to suspect that a determination of nonregulated status of 4114 will lead to higher frequencies of *Bt*-resistant corn rootworm populations than use of the currently available varieties.

## **Issue 12**

A commenter stated that a determination of nonregulated status of 4114 Maize will increase the development of herbicide-resistant weed populations (e.g., “APHIS fails to provide any assessment of the special proclivity of HR crop systems, or 4114 Maize in particular, to trigger evolution of resistant weeds.”), thus worsening the presence of herbicide-resistant weeds in corn production and increasing the costs of herbicide weed management (e.g., “APHIS provides no meaningful assessment of the costs to farmers or U.S. agriculture from the reasonably foreseeable evolution of weeds resistant to glufosinate of 4114 Maizemaize is deregulated”).

Another comment expressed a similar concern that APHIS, in accounting for reasonably foreseeable impacts of weed resistance, had failed to analyze the likelihood and impact of weeds becoming resistant to both glufosinate and glyphosate as a result of changes in use following deregulation. The commenter expressed the view that the assumptions that growers will take steps to manage weed resistance in their fields by means of weed management strategies was unsupported by the facts and contradicted by APHIS own admission in the DEA that cultural practices such as crop rotation have not been followed. The commenter implied that APHIS failed to adequately consider that poor weed management by some growers can result in the development of exceptional weed resistance and that the practice of consecutive planting of corn, overstates the role of crop rotation as a management tool especially when rotated crops are resistance to same herbicides.

## **APHIS Response**

APHIS disagrees that a determination of nonregulated status of 4114 Maize will increase the development of herbicide-resistant weed populations, thus worsening the presence of herbicide-resistant weeds in corn production and increasing the costs of herbicide weed management when compared to the no action alternative. The commenter asserted without supporting information that a determination of 4114 Maize, itself, will increase the development of herbicide-resistant weed populations. As stated throughout the EA, the glufosinate-resistant trait in 4114 Maize is already present in currently available, corn-hybrid varieties (e.g., 1507, 59122, and 1507 x 59122 corn). Because this identical glufosinate-resistant trait is already established in the U.S. corn market, there is no reason to suspect that a determination of nonregulated status of 4114 Maize, itself, will lead to an increase in the development of herbicide-resistant weed populations any more than these existing glufosinate-resistant corn hybrid varieties because the same glufosinate use practices can be applied as these existing corn hybrid varieties.

Weeds resistant to herbicides are generally known to cause the adverse impacts that the commenters have identified, namely increased use of herbicides, increased use of tillage, abandonment of conservation tillage, increase in conventional tillage, and increased cost of weed control. However, maintaining the long-term efficacy of any herbicide is outside the scope of the EA and the authority of APHIS. Because GE crops allow weeds to be so effectively

controlled, they substantially mitigate the adverse impacts growers currently face. There are no substantive data, information, or models that provide a prescriptive determination on the evolution of herbicide resistance in specific weeds or the efficacy of a particular management strategy to prevent the evolution of resistance.

APHIS is also not aware of any models that simulate the evolution of weed resistance in herbicide-resistant agricultural systems. What can be generally observed, however, is the influence a management strategy exerts in the evolution of herbicide resistance in weeds. With regard to corn varieties stacked with resistant traits, it is unlikely that this GE-hybrid corn variety would alter any baseline influence of established management strategies that are currently practiced in GE-corn cultivation systems. Thus, it is unlikely that any GE-hybrid corn variety stacked with 4114 Maize would increase the incidence of resistant weeds, as the factors resulting in resistance in weeds would remain unchanged. Chemistry of the applied herbicide (e.g., glyphosate) and the frequency and rate of application would remain unchanged, as any progeny GE-corn variety containing both the 4114 Maize trait and the herbicide-resistant traits would possess the same trait as its parent variety, and thus, require similar weed management

A variety of genetic, biological/ecological, and operational factors contribute to the evolution of herbicide resistance in weeds. Genetic factors include the frequency of genes in a particular weed species that promotes resistance to a particular herbicide, the mechanism of resistance and the capacity of genes to facilitate this resistance, how resistance is inherited, and the fitness of the weed in the presence and absence of the herbicide (Georghiou and Taylor, 1986); (Neve, 2008). Biological/ecological factors include the method of weed reproduction, seed production capacity, seed bank turnover, and the amount and frequency of gene flow between weed populations (Jaseniuk et al., 1996); (Maxwell and Mortimer, 1994). Collectively, these issues illustrate that different plant species may present different risks of resistance. Operational factors influencing development of weed resistance include farm-level management practices such as the chemistry of the applied herbicide and its respective mechanism, olfaction, and the application rates/frequency of herbicide application (Georghiou and Taylor, 1986); (Jaseniuk et al., 1996).

APHIS disagrees with the premise that the role of management strategies, agricultural information, and voluntary stewardship measures in controlling resistant weeds has been overstated.

APHIS is not relying on management strategies, to stem the evolution and adverse environmental impacts of resistant weeds. However, weed management is an important part of any agricultural system, and growers have increasingly adopted integrated weed management techniques that prolong the usefulness and benefits of the technology. The commercialization of corn varieties stacked with herbicide resistant traits would permit existing and widely-adopted management strategies to continue. Management recommendations to mitigate the development of resistant weeds are guidance, and although a reasonable informed grower would be fully expected to read, know and follow such guidance to maintain safety and effectively achieve desired production results, as guidance they are not enforceable in the absence of a specific contractual obligation.

Recommendations for production of any crop are just one source of information and other sources of information are available to informed growers. Farmers have strong financial and practical interests in managing weeds effectively to reduce the selection of herbicide-resistant weeds and to maximize yield potential. There is general awareness among growers of the need to minimize the potential for development of resistance. Farmers are also generally aware that they will pay more for weed control when herbicide-resistant weeds are prevalent, and given the general agricultural information available to them, it is reasonable to expect an informed grower to take a long-term view towards more sustainable practices and management to prevent or delay the onset of resistance in his or her fields, especially if there are limited cost effective alternatives. It is unfortunate that some growers may take a short-term view, and so may be negligent, risking future weed problems and additional financial costs. However, such practices do not undermine the strategic value of effective weed management strategies applied in accordance with EPA label requirement to the informed grower.

### **Issue 13**

A commenter stated that 4114 Maize volunteers expressing multiple herbicide resistance will require substantial use of, and overreliance on the few remaining herbicides, which in turn will accelerate evolution of resistance to that herbicide in weed populations. Another commenter stated that APHIS does not consider the environmental or economic costs caused by increased use of tillage or herbicide mixtures in order to control corn volunteers resistant to both glyphosate and glufosinate. The commenter referenced a 2012 publication by Avila-Garcia et al. (Avila-Garcia et al., 2012) as evidence.

One commenter indicates that the DEA failed to adequately analyze the likelihood and impact of increased costs associated with resistant weeds, and the reasonably foreseeable impacts of stacked 4114 Maize. The commenter suggested that APHIS, in failing to analyze the impacts of such stacking, erroneously relied on the PPRA conclusion, a conclusion which the commenter stated is contrary to NEPA and APHIS' broad statutory mandate, since such stacking is foreseeable, and creates significant cumulative impacts caused by the cycle of resistance and increased herbicide.

The commenter also expressed concern about the issue of volunteer corn, stating that the discussion of volunteer corn in the DEA was inadequate and unnecessarily abbreviated in its analysis of foreseeable impacts when discussing the problem of volunteer control options and the economic implications of growers having to resort to conventional mechanical means of control. The commenter suggested that APHIS failed to evaluate the economics of controlling volunteers and the effectiveness of conventional options, as foreseeable impacts to the environment and to the economic health of American corn farmers.

The commenter also suggested that APHIS has failed to adequately estimate the cost of controlling volunteer corn despite APHIS' own admission in the DEA that the effective use of herbicides on 4114 Maize hybrids volunteers will depend on whether progeny carry, are stacked with, or contaminated with a resistant trait.

### **APHIS Response**

APHIS disagrees with the comment. As stated throughout sections 2, 4, and 5 of the EA, the glufosinate-resistant and/or glyphosate-resistant traits in 4114 Maize or future breeding stacks of 4114 Maize, are already on the market as phenotypically identical or similar corn hybrid varieties. The commenter provided no basis for the assertion that a determination of nonregulated status of 4114 Maize will lead to a substantial use and overreliance on herbicides to control 4114 Maize volunteers in comparison to phenotypically similar or identical corn hybrid varieties that are already being cultivated in the United States. Therefore, because a determination of nonregulated status of 4114 Maize will not lead to a substantial use management practices (including herbicide use) beyond what is already occurring in the No Action Alternative, it will not lead to any changes to the economic costs farmers experience when managing volunteer corn varieties that are phenotypically similar or identical to 4114 Maize.

Another consideration is that because corn hybrid varieties that are phenotypically identical or similar to 4114 Maize are currently cultivated in and enter U.S. market, there is no reason to suspect that a determination of nonregulated status of 4114 Maize will lead to any herbicide-resistant trait combinations that are not already possible. The commenter even recognized this fact (e.g., "...though there is no reason to believe it should lead to options that would not be obtainable through breeding with 1507 x 59122 under the No Action alternative"). Therefore, there is no reason to suspect that a determination of nonregulated status of 4114 Maize will accelerate the development of herbicide resistant weed populations more than what is possible under the No Action Alternative.

APHIS has analyzed the socioeconomic impacts of adopting 4114 Maize and its hybrids and estimated a net benefit to the grower. Growers will make decisions as to whether to grow 4114 Maize or other corn varieties based upon farming economics. If weeds, volunteers and pest resistance become so prevalent that 4114 and its hybrids are no longer profitable, the resulting socioeconomic and environmental impacts, the baseline of corn growing economics will not materially change as a result of 4114 Maize. .

APHIS' analysis of the "harms" of 4114 Maize and their pathways is discussed in the EA. Based upon the analysis in the EA and the associated plant pest risk assessment, APHIS does not agree with the characterization of 4114 Maize as a potential noxious weed or as a "pathway" for resistant weed development. Volunteer GE corn is no weedier than conventional corn. APHIS has never listed a plant species as a noxious weed for the sole reason that it has acquired resistance to a single herbicide, much less a plant species that is widely and deliberately planted by thousands of farmers. Doing so would significantly dilute the meaning of "noxious weed," hamper APHIS' need to focus resources on truly aggressive, invasive, and damaging plants, and abuse the original intent of the PPA.

APHIS does not expect 4114 Maize to cause significant impacts on the development of herbicide-resistant weeds or significant cumulative impacts when combined with other available herbicide-resistant crops. Therefore, APHIS reasonably concludes that the introduction of alternative tools, such as 4114 Maize, merely provides additional options for growers, and should not have any effect on the rate of development of herbicide resistant weeds.

## **Issue 14**

A commenter stated that “APHIS’ assessment of weed resistance is faulty in part because it relies much too heavily on pesticide industry sources and academics who conduct research for pesticide seed firms.” The commenter also expressed the view that APHIS’ PPRA process violates the PPA and is in contravention of the Presidents Memorandum of March 9, 2009, entitled “Scientific Integrity”, which delineates the core principles of sound science. The commenter indicated that the Agency has illegally limited the scope of its analysis by effectively excluding significant harms likely to injure plants, failing to base its deregulations decisions on sound science, over relying on information provided by the applicant, relying on its own speculation, ignoring high quality data and peer-reviewed literature, failing to critically review the applicant’s claims and information provided, and failing to adequately analyze the socio-economic impacts. The comment asserted that APHIS, in making the assumption that 4114 Maize’s trait is the “functional equivalent” to traits already available in the market, has failed to use sound science and has erroneously relied on outdated environmental documentation in making the assumption that this new trait was relatively safe, when compared with previously deregulated GE corn. The commenter indicated that APHIS must properly inform its PPRA determination with the required NEPA analysis to support its NEPA findings, and that in its current form as applied to 4114 Maize, corn, it is prone to mistakes and based upon unsound science.

## **APHIS Response**

APHIS disagrees with the suggestion that it failed to base the DEA on sound science. APHIS’ analysis and decision within the PPRA regarding the plant pest risk posed by 4114 Maize is based on the best available scientific and technical information. APHIS used sound science to inform its regulatory decision regarding the plant pest risk of 4114 Maize, and has determined that 4114 Maize is not a plant pest risk.

APHIS carefully reviewed the information provided by the petitioner and others and considered all other relevant information sufficient to make the determination on whether to deregulate the 4114 Maize. APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the DEA developed for Pioneer 4114 Maize is adequate and sufficient. The DEA follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA. In making an informed decision under NEPA of potential environmental impacts, APHIS used the best available scientific information, data and expert advice.

In the DEA, APHIS has considered opposing views, has reviewed data submitted by those who supported or opposed deregulation, and has not relied on biased information. APHIS has included an extensive analysis of the socioeconomic impacts of each of the alternatives evaluated and used the best available information from various sources, including peer-reviewed scientific literature that was reviewed and incorporated into APHIS’ analysis. Some of this information was information provided by the petitioner, but considerable information was derived from other sources, including as noted peer-reviewed scientific publications.

APHIS has relied on a variety of sources to support its analysis of the potential impacts of a determination of nonregulated status of 4114 Maize including those pertaining to herbicide weed resistance. These sources include, but are not limited to the Pioneer petition, Federal agencies, and peer-reviewed literature. The DEA acknowledges the complex and multi-disciplinary nature of analyzing and managing potential economic negative impacts of unwanted traits in GM-sensitive, organic or other conventional corn. The DEA does contain reasonable assumptions as needed for the purpose of conducting NEPA analyses. NEPA requires the use of the best available science, and allows for the use of reasonable assumptions for the purpose of analysis, given that they are disclosed and supported. APHIS recognizes the importance of peer-reviewed research publications in its analyses, but APHIS also considers relevant information from sources that do not go through a peer-reviewed process. In plant breeding of new crop varieties, much of the research is never published in peer-reviewed journals, yet it is entirely valid in evaluating the characteristics of the plants being developed. The analyses in the DEA utilize a variety of sources in addition to the 4114 Maize petition. A complete list of references used to support development of the DEA can be viewed in the bibliography located in Chapter 8 of the DEA.

### **Issue 15**

A commenter stated that “APHIS provides no assessment of IWM systems or non-chemical tactics as an alternative to deregulation of 4114 Maize for the stated purpose of DuPont Pioneer’s product, to provide a means to control glyphosate-resistant weeds.”

### **APHIS Response**

The DEA was prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of 4114 Maize. APHIS assembled a list of alternatives that might be considered for 4114 Maize. The Agency evaluated these alternatives, consistent with its authority under the plant pest provisions of the PPA, and the regulations at 7 CFR parts 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives required further consideration for 4114 Maize. As described in Chapters 3.1 and 3.2 of the DEA, APHIS evaluated two alternatives; (1) no action and (2) determination of nonregulated status of 4114 Maize in the environmental consequences section of the EA (Chapter 4). In addition, APHIS rejected several other alternatives. These alternatives are discussed briefly in Chapter 3.3 of the DEA along with the specific reasons for rejecting each.

APHIS did not consider the general nature of organic agriculture and integrated weed management systems as an alternative in the DEA because the nature or use of these practices is not within the scope of analysis of this EA or the APHIS regulatory decisions in response to a petition for deregulated status for 4114 Maize. The DEA has been prepared to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of 4114 Maize. The potential impacts of APHIS’ regulatory decision with respect to non-GE, organic and specialty corn production systems are presented in Chapter 2.2.3 and 4.2.3 of the DEA.

### **Issue 16**

A commenter stated that APHIS provides no critical assessment of voluntary stewardship efforts to forestall weed resistance touted by Pioneer, “despite the failure of similar plans in the past.”

### **APHIS Response**

A stewardship plan is not required for regulatory review of herbicide-resistant crops. However, major developers provide these for the benefit of their customers and to serve the broader needs of agriculture. In some cases, APHIS may note in an EA that a developer has published a required stewardship plan in connection with a Technology Use Agreement. For this herbicide resistant variety, Pioneer notes, “In the foreseeable future, 4114 Maize could be stacked with additional, current or future herbicide traits. In this case, it would be important to develop an appropriate stewardship plan for these products” (Pioneer, 2011a). Although there is no specific plan for 4114 Maize, Pioneer’s recommendations have been published for weed management on glufosinate-resistant crops (and for glyphosate-resistant ones with which it is likely also to be stacked) on a website for grower use (<https://www.pioneer.com/home/site/us>). For each herbicide chemistry, specific recommendations are provided for combination use of multiple herbicides (Pioneer, 2013a), which is one useful technique for slowing weed resistance among several. The website succinctly summarizes their weed resistance management plan, in which they recommend using several herbicides with different modes of action, either as tank mixes or sequentially, multiple weed management practices such as rotation, and mechanical cultivation (Pioneer, 2013b). All are commonly recommended by state extension services and weed scientists (Knezivic, 2010) (Gunsolus, No Date).

The recent experience of global herbicide use clearly shows that resistance in weeds will eventually occur, because plants utilize numerous mechanisms to resist herbicide applications (Vencill et al., 2012). Given typical methods of application, growers will select for these resistant weeds; resistance will be manifested at different rates depending on the herbicide and the plant (Vencill et al., 2012).

In reference to the “failure of similar plans in the past,” the recent history of herbicide-resistant crop use is marked by grower’s having had insufficient encouragement to use comprehensive methods of weed control, since the seed developers were promoting simplicity of over the top applications of mostly a single herbicide on resistant crops (Hartzler, 2003). Now that glyphosate resistance is clearly evident, growers are receptive to the use of newly emphasized techniques to slow development of weed resistance (Prince et al., 2012). Increasingly more research is being done to provide integration of multiple methods to deter resistance, and not reliance on chemical control alone (Harker and O'Donovan, 2013). For example, new research suggests the value of rotating crops and even rotating crop resistance traits because they notably decrease weed diversity (Young et al., 2013). Such strategies are likely to increase the success of the proposals that would forestall weed resistance.

### **Issue 17**

One commenter stated that APHIS’ conclusion that 4114 Maize will not contribute to climate change is based upon the unsupported assumptions that deregulation of 4114 Maize will promote conservation tillage, and is erroneous because the agency fails to base its conclusion on the best available scientific information. The commenter also stated that APHIS also based its

conclusion on the assumption that the practice of no-till has the net effect of carbon sequestration. The commenter further stated that APHIS ignores the effect that 4114 Maize will have upon corn acreage, increased herbicide use, how change in the corn variety will change herbicide use, and that the agency does not provide support for the assertion that label restrictions will prevent environmental damage. The commenter characterizes APHIS' climate change discussion as lacking specificity, technical support, and discussion on the effects of market forces. The commenter states that the lack of discussion of these issues combined with the paucity of analysis of climate change data, of the increase in mycotoxin contamination as a result of drought, of associated water usage required for glufosinate use, and of climate change impacts that are already occurring, demonstrates an insufficient NEPA analysis.

### **APHIS Response**

APHIS recognizes and understands that agricultural activities (including, but not limited to tillage and other management strategies) contribute to the release of GHG emissions that may affect global climate change. However, the DEA was written in response to Pioneer's petition for the determination of nonregulated status of 4114 Maize, and not to address the effects of agriculture or GE crop production systems on global climate change. APHIS directs readers to Chapter 2.2.4 of the DEA for a discussion of climate change and agriculture. It is prudent to mention, however, that management practices between 4114 Maize and currently available corn varieties are unlikely to be dissimilar, considering the likelihood of stacking 4114 Maize with other corn events that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA (as described in Chapter 4.10 of the EA), and the almost universal adoption of GE-corn production systems in the U.S. A conventional paradigm generalizing the relationship between conservation tillage strategies and GHG emissions is dependent on a number of factors, including geographic location, soil structure, moisture availability, and agronomic management practices. Given the variability of these parameters, tillage impacts may be beneficial, neutral, or detrimental.

As stated in Chapter 4 of the EA and the Pioneer 4114 petition, 4114 Maize is likely to be stacked with GE traits that have previously been determined to no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA, such as readily available glyphosate-resistant and *Bt* traits. As discussed in Chapters 2.1.1, 4.3.1.1, 4.3.1.2 of the EA, 4114 Maize is also unlikely to increase corn acreage beyond projected values. Thus, any increase in pesticide usage beyond that associated with projected corn acreage increases (USDA-ERS, 2011) caused by 4114 Maize is unlikely, because any variety containing 4114 Maize can be viewed as a replacement product for corn varieties that already require similar pesticide application strategies and that expectation that 4114 Maize itself is unlikely to increase corn acreage.

### **Issue 18**

A commenter indicated that APHIS's failure to consider reasonable alternatives is contrary to law and inconsistent with APHIS' approach to regulating other GE herbicide-resistant crops. The commenter suggested that the two alternatives that APHIS did consider are mirror-images in their effects, and that APHIS' analysis falls short of the reasonable alternative analysis required by NEPA. The commenter further stated that APHIS has the authority to approve a petition in

part and APHIS' self-imposed limitation is in contradiction to the ruling in Humane Society v. Department of Commerce 432 F. Supp. 2d 4, 23 n.13 (D.D.C. 2006), in which the court recognized APHIS's authority to deregulate a GE crop in part, the court establishing the principle that an Agency's consideration must be more than a "pro forma" ritual. The commenter asserted that, as applied to the present case of 4114 Maize, APHIS has the potential to reduce the impacts of 4114 Maize by analyzing and adopting one or more of the rejected alternatives.

## **APHIS Response**

The DEA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of 4114 Maize. APHIS assembled a list of alternatives that might be considered for 4114 Maize. The agency evaluated these alternatives, consistent with the agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for 4114 Maize. As described in Chapters 3.1 and 3.2 of the EA, APHIS evaluated two alternatives: (1) no action and (2) determination of nonregulated status of 4114 Maize in the environmental consequences section of the EA (Chapter 4). In addition, APHIS rejected several other alternatives. These alternatives are discussed briefly in Chapter 3.3 of the DEA along with the specific reasons for rejecting each.

As described in Chapter 3.3.3 of the EA, several "in part" alternatives were considered but rejected, each for the same reason. APHIS has determined that 4114 Maize is not likely to pose a plant pest risk, thus, the only reasonable alternative to nonregulated status would be the no action alternative; additional consideration of any other alternative would have been arbitrary. For example, geographic restrictions were rejected as an Alternative and not analyzed in detail because, based upon the scientific evidence presented, APHIS had no basis to conclude that 4114 Maize would exhibit plant pest characteristics in certain geographic areas and not others. Consequently risk in any geographically restricted area. Therefore, a Geographic Restriction Alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the PPA, regulations in Part 340 and the biotechnology regulatory policies of the Coordinated Framework.

A regulated GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 when it has been demonstrated, and the Administrator has determined, that it does not present a plant pest risk. The petitioner requesting deregulation of a product is required to provide certain information which the agency uses to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism from which it was derived. If, based on the information, the agency determines that the regulated article is unlikely to pose a plant pest risk, then the agency no longer has a legally justified reason to regulate the article as a plant pest and the article must be granted a determination of nonregulated status. In this case, APHIS has determined that 4114 Maize is not a plant pest (Appendix A of the DEA) and therefore, the product will be granted a determination of nonregulated status.

APHIS has prepared the DEA to consider the potential environmental effects of the proposed action (deregulation of 4114 Maize) and the reasonable alternative to that action (including the no action alternative to continue to regulate 4114 Maize) consistent with NEPA requirements (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). This DEA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from the deregulation of 4114 Maize. In addition, APHIS also has no reason to believe, based on the DEA, that the deregulation of 4114 Maize would cause significant impacts on the environment and therefore, APHIS does not need to prepare an EIS before deregulating this product. APHIS has been reviewing petitions for deregulation since 1992 and has considered a wide variety of species including tomato, corn, cotton, soybean, canola, squash, papaya, and plum. Although APHIS regulations (7 CFR part 340.6(d) (3) (i)) allow for an "in part" determination, such a determination is made relative to plant pest risk. APHIS has found that 4114 Maize does not present any plant pest risk. Therefore, APHIS has no basis to continue to regulate the corn "in part" and also deregulate the corn "in part."

### **Issue 19**

One commenter expressed the opinion that the DEA fails to independently analyze the potential harm to plants, wildlife and humans from glufosinate as a result of stacking and hybridization of 4114 Maizecorn, and the resulting changes to farming practices. The commenter stated that APHIS avoided the issue of reasonably foreseeable increased glufosinate as a result of 4114 Maize commercialization, explaining that federal courts have repeatedly held that an agency is not exempt from analyzing the effects of herbicides under NEPA simply because the herbicide is registered under FIFRA. The commenter stated that the EPA's analysis of glufosinate is dated and that APHIS' reliance upon such outdated information fails to meet its independent duty under NEPA to analyze all reasonably foreseeable impacts. The commenter further indicated that APHIS should delay the deregulation pending future EPA re-registration of glufosinate and that the DEA improperly relies on EPA's registration in failing to adequately address the harm to human health and farm workers from reasonably foreseeable glufosinate use. The commenter asserted that APHIS's conclusion of no additional impacts ignores the likely change in mode and frequency of herbicide application and use of other chemical herbicides to control volunteers.

### **APHIS Response**

**APHIS disagrees with the commenter's assertion that glufosinate use will increase as a result of the deregulation and commercialization of 4114. The commenter is in error: products that are phenotypically identical to 4114 (e.g., 1507 and 59122) are already on the market. Therefore, farming practices are not expected to change due to the deregulation of 4114. As stated above in APHIS Response Issue 5, the amount of herbicide use in general and glufosinate use in particular is not expected to change as a result of the deregulation of this product. Therefore the "potential harm to plants, wildlife and humans from glufosinate as a result of stacking and hybridization of 4114 Maize and the resultant changes to farming practices" that the commenter presents as a concern do not exist. The commenter asserts, with no rationale, that the decision on this petition will change farming practices, including an increase in glufosinate use.**

APHIS acknowledges that the EPA is currently reviewing its registration of glufosinate. The reader is referred to the EPA docket for glufosinate for the most recent information. (EPA-HQ-OPP-2008-0190) at <http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2008-0190>. APHIS uses the most current information throughout the EA. APHIS also acknowledges that the EPA's review is pending throughout the EA. APHIS relies on the EPA's risk assessments and expertise because these are the best available information. APHIS uses this and other information from the scientific literature in its assessment. APHIS' decision on the petition is based on the plant pest risk of the subject organism. It is a decision independent of the decision to reregister glufosinate, which is being made by EPA. APHIS disagrees with the commenter that the agency should delay its regulatory decision while EPA's regulatory decision is pending because EPA's decision will not affect the plant pest status of 4114 Maize.

Stacking of traits is not expected to change an assessment of no significant impact since the component traits of 4114, 1507 and 59122, are already nonregulated, currently on the market, and being grown. If risk assessments of two or more traits have been determined to have no significant impact, then the combination of these traits into a stacked combination are considered to be unlikely to have a significant impact, either (De Schrijver et al., 2007).

The DEA follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA. In making an informed decision of potential environmental impacts, APHIS used the best available scientific information, data and expert advice. The DEA provides thorough review of the need for action, the issues, alternatives, and environmental consequences. APHIS also reviewed and carefully considered all comments submitted by respondents to the public involvement efforts. The agency followed CEQ NEPA regulations and Agency NEPA implementing procedures. APHIS has determined that the analysis in its DEA shows no significant impact on the quality of the human environment from a determination of nonregulated status of 4114 Maize and that APHIS does not have to prepare an environmental impact statement (EIS).

The Coordinated Framework, published by the Office of Science and Technology Policy (51 FR 23302, 57 FR 22984), describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products, and explains how federal agencies will use existing federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The U.S. Food and Drug Administration (FDA) regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* (FR) on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of food derived from GE products. Pioneer has

provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products.

EPA regulates all pesticides under FIFRA, and APHIS does not anticipate any changes from the use of glufosinate on corn. APHIS has carefully considered the possible environmental impacts of the proposed action, and is satisfied that the DEA prepared by APHIS is adequate and sufficient. The issue of potential increased herbicide use and the effects upon plants and animals was discussed in the DEA. Therefore, as discussed in the DEA, based on APHIS' review of field and laboratory data and scientific literature, and safety data available on other GE corn, APHIS has concluded that a determination of nonregulated status of 4114 Maize would have no significant impacts on human health. As discussed in the DEA, APHIS also has concluded that a determination of nonregulated status of 4114 Maize would have no significant impacts on animal feed or animal health.

## **Issue 20**

One commenter maintained that APHIS has arbitrarily limited what constitutes a plant pest risk by erroneously constraining its analysis in both the DEA and the PPRA. The commenter notes that APHIS regulations at 7 CFR part 340 establish APHIS' authority to grant or deny petitions to deregulate in whole or part upon a determination of plant pest risk. The commenter further stated that given such authority, APHIS' analysis has not adequately addressed the risk presented by 4114 Maize posed by numerous environmental, economic, and health risks, including the risk of transgenic contamination, increased herbicide use, herbicide resistant weeds, and resistance to the *Bacillus thuringiensis* trait.

The commenter further criticized APHIS for failing to exercise its inherent authority to consider noxious weed risks. This alleged failure to act on the part of APHIS was characterized by the commenter as being inconsistent and contradictory when considered in terms of other APHIS regulatory actions specifically addressing traditional noxious weeds and the definition of noxious weeds under the PPA. The commenter explained that APHIS' authority under the PPA is broad, as the term "harm" includes both direct and indirect harm encompassing weeds and their pathways. The commenter stated that the DEA is impermissibly narrow, predetermined, and silent on the indirect noxious weed risks presented by hybrid resistant weeds characterized as "superweeds", despite APHIS' own acknowledgement of the problem and its statutory mandate to consider all aspects of preventing noxious weed harm and plant pest risks. Under NEPA, APHIS cannot define the project scope so narrowly that it forecloses consideration of reasonable alternatives.

## **APHIS Response**

APHIS regulations were promulgated prior to the consolidation of the Noxious Weed Act and the Plant Pest Act into the Plant Quarantine Act. However, the PPA maintained the separate regulatory framework for plant pests and noxious weeds that were originally promulgated under the Federal Plant Pest Act and the Federal Noxious Weed Act, and as stated in Center for Food Safety v. Vilsack No 12-15052, D.C. No. 3:11-cv-01310-SC, opinion of the United States Court of Appeals for the 9<sup>th</sup> Circuit, "neither the PPA nor APHIS's regulations, ... require APHIS to conduct a separate noxious weed analysis in response to a party's petition to deregulate a plant

pest under 7 CFR section 340.6". If a person wishes to have APHIS consider whether a particular plant is a noxious weed, that person may petition the agency pursuant to the process contained at 7 C.F.R. part 360.

While the noxious weed definition in the PPA includes many kinds of physical harms beyond harm to other plants (e.g. harm to public health and the environment), the commenter misinterprets the level of impacts that would warrant APHIS to determine a plant to be a "noxious weed" precipitating Federal action. The commenter uses the term "noxious weed" inconsistently with the definition of weeds, which in all likelihood, may not be considered "noxious" under the PPA and prior APHIS authorities. APHIS has explained the distinction between "weeds" and "noxious weeds" as:

"'Weeds,' in the broadest sense of the word, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings may be considered weeds in others. In a narrower sense, weeds are invasive, often non-native, plants which impact natural and managed ecosystems, often with significant negative consequences due to lost yields, changes in management practices, altered herbicide use, etc. Only a fraction of these problematic weeds are considered to be so invasive, so harmful, and so difficult to control that Federal regulatory intervention to prevent their introduction or dissemination is justified, and these are the focus of the regulatory controls placed on them by APHIS" [73 Fed. Reg. 60008, 60013 (Oct. 9, 2008)].

APHIS' analysis of the "harms" of 4114 Maize referenced by the commenter relating to weeds, the environment, economics, and health risks are discussed in the DEA in Section 5.10 of the EA. The concerns raised in regard to the risk of "transgenic contamination", increased herbicide use, herbicide resistant weeds, and resistance to the *Bacillus thuringiensis* trait are discussed in APHIS' response to Issue 4.

APHIS' analysis of the "harms" of 4114 corn referenced by the commenter caused by weeds is discussed in the DEA.

The comment also expressed the concern that herbicide use associated with 4114 Maize will create a pathway to the development of noxious weeds, so supports continued regulation of 4114 Maize as a noxious weed under existing authority. This once again misinterprets what would be considered a noxious weed. According to the commenter's theory, the corn would be considered a noxious weed because a plant that might germinate beside it might become more difficult to kill or develop a resistance to an herbicide. Nonetheless, the issue of the risk of herbicide-resistant weeds is addressed in the DEA, and APHIS finds no basis for such concern in regard to 4114 Maize. Although plant species have and will continue to develop resistance to certain herbicides when used in agriculture, APHIS has never made a determination to regulate a plant species as a noxious weed, solely on the basis that the plant has acquired resistance to an herbicide. As with any weed species that evolves resistance to an herbicide, APHIS will consider that herbicide resistance along with other factors such as invasiveness, significance of damage, and difficulty of control in determining whether to use Federal authority to prevent its dissemination.

## **Issue 21**

One commenter criticized APHIS' NEPA process as being structurally incorrect and backwards. According to the commenter, APHIS had begun its NEPA analysis with the erroneous conclusion that the PPRA determination that 4114 Maize was unlikely to pose a plant pest risk, a finding which dictated APHIS's unconditional deregulation. The commenter believes this finding inappropriately "confined" and "predetermined" APHIS' NEPA process, because the PPRA should serve to inform NEPA and not direct an outcome. The commenter noted that the PPRA is not a lawful substitute for APHIS's independent duty under NEPA to meaningfully consider other reasonable deregulation alternatives to curtail the rapid evolution of resistant weeds. The commenter suggested that despite APHIS's own acknowledgment of the foreseeable problem of glyphosate-resistant weeds as a result of glyphosate-resistant crop systems, the agency failed to consider other partial deregulation alternatives that would have imposed methods to mitigate the development of resistant weeds. The commenter further questioned APHIS' assertion that stacked 4114 Maize hybrids would not change farmer practices, and that this assertion was not supported by "reasoned analysis" of how a new product, stacked into numerous corn hybrids covering tens of millions of acres of farmland, could not affect farming practices.

#### **APHIS Response**

Once APHIS concludes under the PPRA process that Pioneer 4114 Maize is not a plant pest because it does not cause plant pest injury to plants, the agency has no jurisdiction to continue regulating 4114 Maize, and as such, APHIS' deregulation of 4114 Maize is a nondiscretionary act. APHIS's duty under NEPA "does not expand the jurisdiction of an agency beyond that set forth in its organic statute ..." (See *S. Coast Air Quality Mgmt. Dist. V. FERC*, 621 F.3d 1085, 1092 (9<sup>th</sup> Cir. 2010)). NEPA is used as an administrative means by Federal agencies in conjunction with other relevant information and determinations to plan actions and make decisions (40 CFR 1501.2). NEPA requires a full and fair administrative record and federal agencies are required to make a thorough evaluation to provide for informed decision-making by providing a full and fair discussion of significant environmental impacts to inform decision makers and the public of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment.

The APHIS Plant Pest Risk Assessment (PPRA), a separate process, is a scientifically-based risk analysis and assessment process used by the Agency, which informs and helps identify the range of alternatives to be analyzed in the EA. The PPRA is also used to identify and support the analysis of potential impacts to the human environment. The PPRA is an analysis of potential plant pest risk and is not the final determination on the regulatory status. Factors used in determining an Agency's Preferred Alternative, in addition to economic, environmental and technical considerations, also include the ability to fulfill the agency's statutory mission and responsibilities. To be clear and transparent to the decision maker and the public, APHIS identifies in the NEPA process how its regulatory authority would be carried out under each of the alternatives. By disclosing this information, APHIS ensures that information relevant to its decision making authority is being made available before decisions are made and before actions are taken. Identifying the scope of APHIS' regulatory authority by no means prejudices the agency's NEPA analysis, but provides for and allows for a full and rigorous analysis of potential impacts to the human environment.

With regard to the commenter's assertion that APHIS is incorrect in its assumption that farming practices will not change as a result of the deregulation and subsequent commercialization of 4114, as mentioned in the response to Issue 19, above, there is no reason to believe that the stacked combination of two traits already individually determined to be of no significant impact will change as a result of stacking (De Schrijver et al., 2007).

## **Issue 22:**

One commenter found APHIS' analysis in the DEA of what the commenter characterized as "the threat of transgenic contamination and its interrelated economic impacts" to be insufficient. The commenter suggested that the DEA failed to analyze the likelihood of harm from "transgenic contamination" by means of both pollination and the mixing of GE seed with non-GE seed. The commenter further noting, that APHIS, despite admitting in the DEA that cross-pollination is possible, had failed to properly assess the implication of wind speed in pollen dispersal. While APHIS, as the commenter further noted, at the same time suggested in the DEA that management in seed certification would effectively mitigate such contamination. The commenter also disagreed with APHIS's finding that Pioneer 4114 would presents no greater risk of cross-pollination than conventional corn. The commenter suggesting that APHIS had failed to meet the standard identified in the case of Geertson Seed Farms v. Johnson (Geertson), 2007 WL 518624 at 5 (N.D. Cal. Feb. 13, 2007).

The case of Geertson , according to the commenter, stated that Geerton stands for the proposition that "when transgenic contamination is made possible by deregulation, APHIS has the duty to take steps to disclose, analyze and identify any interrelated adverse effects." The commenter suggested that the agency has "failed to adequately analyze potential gene flow contamination from multiple pathways such as post- mixing". The commenter further indicated that it is difficult to prevent such seed contamination despite efforts to confine production given "the role of human error in such contamination events," and that this assertion was supported by other studies of contamination. The commenter noted that past experience indicates that such management efforts as confinement strategies, best management practices, binding contractual agreements, and explicit conditions have failed in the past because of "unexplained human error" resulting in "significant and widespread" economic harm.

## **APHIS Response**

APHIS has not classified a plant as a "plant pest" based solely on cross-pollination potential because it does not consider such alterations to be a plant pest harm within the meaning of the PPA. In the EA for 4114 Maize, APHIS did meet the standard identified by the District court in Geertson in meeting the procedural requirements of NEPA to take "a hard look" by extensively analyzing the potential for cross-pollination and the direct, indirect, and cumulative impacts of cross-pollination, and also describes the agricultural and biological factors that influence the potential for cross-pollination including pollinators and wind. APHIS recognizes that corn is open-pollinating and it is possible that genes could move via wind-blown pollen to an adjacent field. All corn, whether GE or not, can transmit pollen to nearby cornfields. The administrative record supports the fact that 4114 Maize is not different from conventional corn or other GE corn in terms of pollen viability, and that it is not expected to have an increased ability to cross-pollinate with other corn varieties when compared to other corn varieties that are currently

available for commercial planting. The natural movement of genes through normal cross-pollination is not considered a plant pest harm within the meaning of the PPA.

It is known that an influx of pollen originating from a given corn variety may not appreciably change the characteristics of corn in adjacent fields because gene flow declines as a power of  $1/r^2$  and other factors such as wind speed, host variety and temperature that also affect the results (Aylor et al., 2003), (Jones and Brooks, 1950). For example, in observations of a large number of commercial canola fields, incidence of transgene flow was approximately 0.015 % at a distance of 500 m (see Fig 2 in (Rieger et al., 2002)) and in a smaller corn study, 0.05% at 100m (Goggia et al., 2006).

Methods of spatial and temporal isolation are widely used and accepted when seed producers are seeking to minimize the influx of pollen from sources outside the seed production field. To maintain varietal purity, AOSCA (Association of Official Seed Certifying Agencies) recommends an isolation distance of 200 meters for nearby corn populations to produce certified seed (AOSCA, 2003). These methods are readily applicable to the production of certified organic corn seed. Gene flow rate between corn populations is extremely variable depending on the spatial, temporal, genetic and environmental factors (Brookes and Barfoot, 2004a); (Messeguer et al., 2006). Available experimental evidence indicates that gene flow rates drop substantially (1%) beyond 20 m (Henry et al., 2003); (Ma et al., 2004); (Messeguer et al., 2006). With regard to the issue of post-harvest mixing, as discussed in Section 2.3.2 of the EA, seed handling standards are established by the American Organization of Seed Certifying Agencies (AOSCA) to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA, 2004).

If 4114 Maize is deregulated and receives regulatory approval from all appropriate agencies, Pioneer may make 4114 Maize available to growers and breeders. It is not likely that other farmers who choose not to plant or sell 4114 Maize, such as organic producers, or other transgenic corn varieties, will be significantly impacted by the expected commercial use of this product because (a) non-transgenic corn varieties will likely still be sold and will be readily available to those who wish to plant them; (b) farmers that purchase 4114 Maize will be informed of recommended management practices for cultivation; (c) methods of spatial and temporal isolation are widely used and accepted, and corn seed producers employing them can minimize the influx of pollen from sources outside the seed production field; (d) most of the corn acreage in the United States is already planted to GE herbicide-resistant and/or insect-resistant varieties; (e) APHIS expects that 4114 Maize may replace some of the presently available GE corn varieties without changing the overall corn acreage.

APHIS concludes that organic farmers will be able to coexist with GE-corn producers as they do now. Although such measures as best management practices and stewardship do reduce the potential for cross-pollination and have an important role, APHIS does not conclude that such measures would, in themselves, mitigate all cross-pollination concerns. However, because cross-pollination is not a plant pest risk, applying mandatory mitigation measures to prevent all potential cross pollination exceeds APHIS' authority under part 340, once APHIS has prepared a full plant pest risk assessment and has found that 4114 Maize does not present a plant pest risk.

### **Issue 23:**

A commenter listed a number of concerns relating to the effects of 4114 Maize on conventional and organic corn production. The commenter stated that APHIS' finding that deregulation of 4114 Maize will not have significant interrelated economic impacts is "fundamentally flawed". The commenter asserted that the effects of deregulation on organic and conventional farming are "interrelated and must be considered" in assessing whether such impacts are "significant . . .". The commenter further suggested that APHIS' finding that 4114 Maize is not expected to have a substantial impact on organic corn "ignores the socioeconomic impacts to organic farmers of potential transgenic contamination." The commenter noted that APHIS fails to adequately assess potential impacts, based on the "erroneous assumptions" that organic growers will take steps to protect their crops to maintain the organic price premium, and that the presence of a detectable GE residue would not constitute a violation of the USDA's National Organic standard.

The commenter stated that APHIS "unjustly shifts the burden" of avoiding contamination onto growers of surrounding or adjacent properties. The commenter noted that in doing so, APHIS failed to analyze the potential efficacy of these measures, or even if such measures are sufficient to prevent contamination. The commenter suggested that the DEA effectively shifts all responsibility to third party growers, alleviating the actual producers of GE corn of all responsibility. The commenter noted that APHIS must fully disclose and analyze the socioeconomic impacts of "transgenic contamination" of organic animal feed, and how "transgenic contamination" is creating pressure on the ability of growers to source organic corn because of the "increased difficulty of planting under organic conditions." The commenter criticized the DEA for assuming that organic farmers can rely on measures such as isolation distances and buffer zones to reduce the chance of contamination without the application of restrictions such as post-market limitations or enforced measures that would protect third party farmers. The commenter further noted that the DEA's "silence on the private cost of testing for GE presence" for organic certification "ignores the socioeconomic impacts" that the Supreme Court recognized in *Monsanto v Geertson Seed Farms* (Monsanto), 130 S. Ct. 2743 (2010), whereas the commenter noted, the court held that "potential loss of conventional organic varieties" was an "environmental injury as well as an economic harm". The commenter interpreted this ruling to say "that harm to organic production systems is also harm to the environment and to the ecologically beneficial agricultural model underlying the organic industry as driven by consumer choice." The commenter described a model as "representing the integration of cultural, biological and agricultural practices that foster the recycling of resources, ecological balance, and biodiversity," all values that "lie at the core of the organic industry." The commenter indicated that APHIS' action would eliminate "consumers' right to choice, a socioeconomic effect tied to a physical impact," and as such, APHIS must assess the effect upon the public's "right to choose" and "growers' right to protect the integrity of their production."

The commenter challenged APHIS' statement that the USDA organic standard is a processed-based standard, as being contrary to the public's perception "that organic means GE-free". The commenter further noted that during the Organic Food Production Act implementation, the USDA acknowledged that "consumers have made clear their opposition to the use of [GE] techniques in organic food production," and that the use of genetic engineering in the production of organic food runs counter to consumer protection. The Agency, according to the commenter, "ignores the likelihood that when consumers do become aware of the GE contamination, consumers may likely reject organic food," and that such rejection may have economic impacts to growers who may lose their organic status, which may also result in the loss

of export markets. The commenter suggested that the DEA is silent on how the deregulation of 4114 Maize may affect U.S. export markets, while relying on the premise that producers supplying GE-sensitive markets will take steps to protect their crops. The commenter stated that APHIS “ignores the potential adverse effects of market rejection” as shown from past experiences of market loss such as the development of Bayer LL601 resulting in rice contamination.

### **APHIS Response**

The U.S. Department of Agriculture's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) has released a final set of recommendations on enhancing coexistence among different crop production methods (Ihnen, 2012). The AC21 presented its report to Agriculture Secretary, Tom Vilsack, to be used as guidance to enhance working relationships among farmers growing different types of crops, specifically GE- and non-GE crops. The committee also made recommendations to the USDA emphasizing education, stewardship and good neighbor-to-neighbor communications. The report indicates that technological innovations and market diversity have become key drivers of increased productivity and product quality for all forms of American agriculture. As mentioned in the EA, approximately 88% of all corn planted in the United States in 2012 was GE.

The essential dynamics relating to the principals of coexistence of conventional corn and organic corn production would not change by the deregulation of 4114 Maize. Although producing a particular crop for a specific market and meeting the specifications for growing a product to be marketed could be characterized as a “burden”, this burden is intrinsic to plant production in general and growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields despite the method by which traits were introduced (conventional breeding or recombinant DNA technology). Growers have always had the choice of what crops to grow, and have had to contend with commingling, admixtures, and other unintended material in their crops (Ronald and Fouche, 2006). Studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Brookes and Barfoot, 2004a), (Brookes and Barfoot, 2004b), (Gealy et al., 2007).

Ultimately, organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. A number of techniques have been developed in order to maintain the concept of coexistence and to prevent cross-pollination. Isolation distances between fields help to minimize the effects of pollen flow. In addition to spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination (i.e. plant varieties with different maturity dates) or stagger planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop. Isolation distances, reproductive isolation (e.g., staggering planting dates or growing varieties with differential maturity times), and farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow.

APHIS acknowledges that the public has a right to choose non-GE foods (Anderson, 2008). USDA's goal is to ensure that all forms of agriculture thrive, so that food can remain abundant,

affordable, and safe and thereby promote an individual's choice to purchase or grow food produced by either conventional, GE, or organic methods. APHIS acknowledges that the public may have varying perceptions of the term "organic" and the term often may take on different meanings in the context of advertising, cultural values, pharmaceuticals, chemistry, food, agriculture and contemporary thought as expressed in literature and media. To accommodate the need for an appropriate food standard, the USDA established the National Organic Program (NOP), under the Organic Foods Protection Act and established the National Organic Program regulations. In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program' (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). The NOP prohibits the use of excluded methods in organic operations.

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. Under the NOP, certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2007). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps (such as isolation zones, use of buffer rows surrounding the organic crops, adjusting planting dates, and appropriate cleaning of planting and harvesting equipment) to avoid contact with the products of excluded methods as detailed in their approved organic system plan.

Under NOP regulations, organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. Isolation distances, reproductive isolation (e.g., staggering planting dates or growing varieties with differential maturity times), and farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow. The NOP specifically discusses buffer zones and defines them as areas located between a certified organic production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact with prohibited substances applied to adjacent land areas and the organic grower can incur costs associated with the establishment of these buffer zones. As noted by Ronald and Fouche (Ronald and Fouche, 2006), "While 100% purity (zero tolerance for any undesired components) is very difficult to attain for any agricultural commodity, standard procedures involving spatial separation, border rows, planting dates, maturity dates, cleaning of equipment, and post-harvest handling have traditionally been able to provide products that meet the production burden of supplying products for diverse market requirements."

APHIS expects 4114 Maize will be used to breed corn varieties suitable to a range of environments and replace some of the insect-resistant corn varieties. The effect on agricultural practices (e.g., cultivation, spray programs, crop rotation practices, planting rates, etc.) from its introduction into the environment should not be significantly different than for the previously

deregulated herbicide-resistant corn lines already in agricultural production, and the baseline of effects would not reasonably be expected to change. NOP-approved practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement these practices (Ronald and Fouche, 2006),(Fernandez and Polansky, 2006),(Anonymous, 2010).

Major buyers of organic commodities have allowances for a certain percentage of GE traits. While some buyers may require testing for unintentional GE-trait content, this is one of the costs that presumably makes organic products more costly at purchase, and for which the grower is reimbursed. It is not likely that organic farmers or other farmers who choose not to plant transgenic varieties or sell transgenic grain will be significantly impacted by the commercial use of 4114 corn. Non-transgenic corn will likely still be sold and will be readily available to those who wish to plant it. Given this baseline, the potential impact on organic farming should not change from the current situation, and organic or other growers who choose not to plant or sell GE corn (a) will still be able to purchase and grow non-GE corn; (b) will be able to coexist with GE-corn producers as they do now. APHIS therefore finds no basis of a burden being imposed, of burden shifting or an increased burden being placed upon other farmers as a result of the deregulation of 4114 Maize.

## **Issue 24**

One commenter suggests cited concerns with respect to APHIS' cumulative effect analysis, expressing the view that APHIS' analysis fails to use the proper baseline, and that its findings are premised on a number of mistakes and assumptions. Specifically, the commenter identified APHIS' assumptions that the deregulation of 4114 Maize will not result in increased herbicide use, the finding that corn acreage will not increase as a result of market forces, and that 4114 Maize is unlikely to shift agricultural practices from less chemically dependent agricultural cropping to GE-corn cropping systems. The commenter suggested that APHIS mistakenly failed to properly assess what was characterized by the commenter as the "foreseeable increase" of glufosinate use, as a consequence of increased corn planting, , increased glufosinate use, changing farming practices to deal with "foreseeable weeds" which will adapt herbicide resistance to the stacked corn varieties intended for development by Pioneer. The commenter criticized APHIS' analysis of stacked 4114 Maize for ignoring the potential for increased glyphosate use, as well as APHIS' conclusion that it has no duty to assess glyphosate, based on the fact that APHIS had discussed the issue in previous deregulation documents. All conclusions, as the commenter noted, are based on outdated analysis and do not use the best available science. The commenter also indicated that APHIS' assumption that glufosinate will replace and not increase existing herbicide use on corn, is erroneous since the DEA itself recognizes that the issue is a question of some debate, and noted that glyphosate has not eliminated or replaced the use of other more toxic herbicides, as the DEA suggests.

## **APHIS Response**

The commenter suggested that APHIS fails to use the proper baseline in evaluating cumulative effects and asserted that the APHIS analysis was based upon error, mistakes, outdated information and assumptions. These assertions mischaracterize APHIS' PPRA and NEPA

analysis and make a number of inferences that are incorrect. APHIS has seen no evidence, and the commenter provided none, to suggest that weed-resistant concerns as they relate to 4114 Maize are somehow more of a concern, more aggressive and/or more invasive and of a kind to warrant concerns about cumulative effect, given the current baseline of corn production using other GE corn and non-GE corn varieties currently used in agriculture. The scientific evidence does not support such concerns and public policy must be based upon more reasoned, deliberative, scientifically based rationale as that in the PPRA risk-based analysis.

Weeds resistant to herbicides, in the context of agriculture, are biologically driven or selected for by opportunistic plants under the stress of herbicides, and have been an issue since the first introduction of herbicides in the 1940s. Agriculture has been long challenged by the issues of pesticide and herbicide resistance to any agricultural pest or weed management technique. Any strategy will eventually select for survivors and those survivors will biologically prevail and reproduce within the adapted habitat niche. This is the baseline of pest and weed biology that underlies the science of agriculture, and there is no contradiction that growers will have more effective weed control with the initiation of the use of a new chemical technology in an herbicide or insect control with a pesticide use, but that eventually given its general continued use, an eventual resistance problem will arise. This is a primary impetus for the development of new technologies and pest control strategies for crop production. For that reason, it is reasonably foreseeable that growers will need to alter and vary methodology and management techniques to control the weeds or insects as the dynamics of selection cause the need to change agricultural chemistries, strategies and management techniques. APHIS disagrees that it is a flaw to identify the existing baseline of agriculture as a baseline for evaluating 4114 Maize and to accept some level of unknown in identifying future replacement technology.

The commenter also indicated a concern that there is something wrong with the fact that farmers will have to shift agricultural practices in managing their fields as a result of predictable or foreseeable weed resistance. APHIS does not agree that 4114 Maize will shift agricultural cropping practices, will increase overall corn acreage, or effectively change cropping patterns and agricultural practices from less chemically dependent agriculture to more chemically dependent agriculture. Growers choose management practices, including weed resistance management, based on many factors. APHIS cannot control which practices growers will choose, so the agency can only discuss potential outcomes under different management practices. Changes in agricultural strategies, such as the use of multiple herbicide chemistries, is an accepted adjustment to changed conditions and a best management practice to mitigate the selection of resistant weeds.

The commenter also described concerns about the likelihood of increased herbicide use as a result of 4114 Maizecorn. It should be noted that the EPA, not APHIS, regulates the use of herbicides, and has the legal authority to control their use. Herbicide use has increased over the last two decades, and APHIS's regulatory decision on this petition will not materially change that trend. Since herbicide registration and use is under EPA's legal jurisdiction and control, EPA has the regulatory expertise and experience in analyzing and evaluating the likely environmental long-term consequences of increased use. APHIS relies on EPA's analyses to evaluate the potential cumulative effects resulting from its regulatory decisions. In the cumulative impacts section of the DEA, APHIS has included an analysis of past herbicide use and has made some qualitative predictions on future use based on past uses and current trends in

Therefore, the potential environmental effects resulting from the considered alternatives for APHIS' regulatory decision on the petition for nonregulated status is the focus of the DEA.

APHIS has also considered the potential impact from the stacking of herbicide-resistant traits that could result if Pioneer 4114 Maize was to be grown commercially. The factors that were considered in evaluating the potential impact of stacking of herbicide resistance traits were: (1) the availability of deregulated herbicide resistance events; (2) the level of commercial production of each of the events; (3) the effect of stacked traits on the plant and on herbicide use; (4) the number of effective alternative herbicides for corn production; (5) the probability of developing weeds with multiple resistance to various herbicide modes of action; (6) the probability of cross-pollination in the field; (7) the probability of a stacked corn becoming a weed. Based on these considerations as analyzed in the DEA and the attached response to comments, there should be no significant impact from the stacking of herbicide-resistant traits by deregulating this line.

### **Issue 25**

A commenter stated, "APHIS completely ignores the potential socio-economic, cultural, and agricultural impacts faced by farmers in Mexico and other parts of the world where traditional Maize varieties and wild relatives play a crucial role in the socio-economic stability of farmers. In particular, farmers in Mexico are already suffering the effects of genetic contamination from other GE crops, which harm beneficial insects, soil fertility, and impair the availability of natural pesticides. APHIS did not consider the possible impacts that yet another genetic trait can have on farmers in Mexico and around the world where native Maize and wild corn relatives are not only grown, but an indispensable part of their culture and the economy."

### **APHIS Response**

The impacts suggested by the commenter are outside of the scope of this EA. Mexico, as well as many other countries, like the United States, has its own regulatory systems and its own standards for evaluating the environmental effects of Pioneer 4114 Maize.

### **References**

- Anderson G. (2008). Lake County Votes to Ban GMO Crops, *The Press Democrat*.
- Anonymous. (2010) Survey: Organic Farmers Want Seed Tested for GMOs. *Organic and Non GMO Report*, 10(4), 7.
- Anonymous. (2011, September 1, 2011). Cargill Bars Syngenta Corn Variety at U.S. Wet Mills, *Reuters U.S. Edition*.
- AOSCA. (2003) 99% Non-GMO Corn Grain Requirements. American Association of Seed Certifying Agencies. Retrieved March 2011, 2011 from
- AOSCA. (2004) Quality Assurance (QA) Program. The Association of Official Seed Certifying Agencies. Retrieved November 8, 2010 from <http://www.certifiedseed.org/PDF/UGAHosted/QA.pdf>.

- Avila-Garcia WV, Sanchez-Olguin E, Hulting AG, and Mallory-Smith C. (2012) Target-site Mutation Associated with Glufosinate Resistance in Italian Ryegrass (*Lolium perenne* L. ssp. *multiflorum*). *Pest Management Science*, 68.
- Aylor DE, Schultes NP, and Shields EJ. (2003) An Aerobiological Framework for Assessing Cross-Pollination in Maize. *Agricultural and Forest Meteorology*, 119, 111-129.
- Benbrook CM. (2012) Impacts of genetically engineered crops on pesticide use in the U.S. -- the first sixteen years. *Environmental Sciences Europe*, 24(24).
- Brookes G and Barfoot P. (2004a) Co-existence in North American Agriculture: Can GM Crops Be Grown with Conventional and Organic Crops? *PG Economics*.
- Brookes G and Barfoot P. (2004b) Co-existence of GM and Non-GM Crops: Case Study of Maize Grown in Spain. *PG Economics*.
- Brookes G and Barfoot P. (2010) GM Crops: Global Socio-Economic and Environmental Impacts 1996-2008. United Kingdom: PG Economics Ltd. Retrieved from
- Brookes G and Barfoot P. (2012) GM Crops: Global Socio-economic and Environmental Impacts 1996-2010. Dorchester, UK: PG Economics Ltd, UK. Retrieved May 2012, from
- Brookes G, Carpenter JE, and McHughen A. (2012) A review and assessment of "impact of genetically engineered crops on pesticide use in the US - the first sixteen years: Benbrook C (2012)". *Environmental Sciences Europe*, 24(24), 14.
- De Schrijver A, Devos Y, Bulcke Vd, Cadot P, De Loose M, Reheul D, and Sneyers M. (2007) Risk Assessment of GM Stacked Events Obtained from Crosses between GM Events. *Trends in Food Science and Technology*, 1-9.
- Fernandez MR and Polansky A. (2006) *Peaceful Coexistence among Growers of Genetically Engineered, Conventional, and Organic Crops*. Presented at Multi-Stakeholder Workshop. Boulder, Colorado.
- Gassmann AJ, Petzold-Maxwell JL, Keweshan RS, and Dunbar MW. (2011) Field-evolved resistance to BT maize by Western Corn Rootworm. *PLoS One*, 6(7), e22629.
- Gealy D, Bradford K, Hall L, Hellmich R, Raybould A, Wolt J, and Zilberman D. (2007) Implications for Gene Flow in the Scale-up and Commercial Use of Biotechnology-Derived Crops: Economic and Policy Considerations. Washington, D.C.: Retrieved from
- Georghiou GP and Taylor CE. (1986) Factors Influencing the Evolution of Resistance. In, *Pesticide Resistance: Strategies and Tactics for Management*). Washington, D.C.: National Academy of Sciences.
- Goggia AS, Caragea P, Lopez-Sanchez H, Westgate MD, Arritte R, and Clark C. (2006) Statistical Analysis of Outcrossing between Adjacent Maize Grain Production Fields. *Field Crops Research*, 99, 147-157.
- Gunsolus JL. (No Date). Weed Control in Corn. University of Minnesota, Last accessed from <http://appliedweeds.cfans.umn.edu/weedbull/Corn.pdf>
- Harker KN and O'Donovan JT. (2013) Recent Weed Control, Weed Management, and Integrated Weed Management. *Weed Technology*, 27(1), 1-11.
- Hartzler B. (2003) Is Your Weed Management Program Reducing Your Economic Return? Iowa State University Extension Agronomy. Retrieved from <http://www.weeds.iastate.edu/mgmt/2003/economics.shtml>.

- Henry C, Morgan D, Weekes R, Daniels R, and Boffey C. (2003) Farm Scale Evaluations of GM Crops: Monitoring Gene Flow from GM Crops to Non-GM Crops in the Vicinity. Part I.: Forage Maize. Retrieved from
- Hyten A. (2013, May 13, 2013).
- Ihnen D. (2012) Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture. Washington, D.C.: United States Department of Agriculture. Retrieved from
- Jaseniuk M, Brule-Babel AL, and Morrison IN. (1996) The Evolution and Genetics of Herbicide Resistance in Weeds  
*Weed Science*, 44, 176-193.
- Jones MD and Brooks JS. (1950) Effectiveness of Distance and Border Rows. Retrieved from
- Knezivic S. (2010). Use of Herbicide-Tolerant Crops as Part of an Integrated Weed Management Program. University of Nebraska, Lincoln. Last accessed 5-16-13, from <http://www.ianrpubs.unl.edu/epublic/live/g1484/build/g1484.pdf>
- Ma BL, Subedi KD, and Reid LM. (2004) Crop Ecology, Management and Quality: Extent of Cross-Fertilization in Maize by Pollen from Neighboring Transgenic Hybrids. *Crop Science*, 44, 1273-1282.
- Mahon RJ, Downes SJ, and James B. (2012) Vip3A resistance alleles exist at high levels in Australian targets before release of cotton expressing this toxin. *PLoS One*, 7(6), e39192.
- Maxwell BD and Mortimer AM. (1994) Selection for Herbicide Resistance. In, *Herbicide Resistance in Plants: Biology and Biochemistry* (pp. 1-25). SB Powles and JAM Holtum (Eds.). Boca Raton, Florida: Lewis Publishers.
- Messeguer J, Penas G, Ballestar J, Bas M, Serra J, Salvia J, Palaudermas M, and Mele E. (2006) Pollen-Mediated Gene Flow in Maize in Real Situations of Coexistence. *Plant Biotechnology Journal*, 4, 633-645.
- Neve P. (2008) Simulation Modeling to Understand the Evolution and Management of Glyphosate Resistance in Weeds. *Pest Management Science*, 64, 392-401.
- OECD. (2002) Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides, and Biotechnology. Paris: Retrieved 20 August 2002, from
- Pioneer. (2011a) Petition for Determination of Nonregulated Status for insect-resistant and herbicide-tolerant 4114 maize. Submitted by N Weber, Regulatory Affairs Manager. Pioneer Hi-Bred International, Inc. DuPont Agricultural Biotechnology (See Table: [http://www.aphis.usda.gov/biotechnology/not\\_reg.html](http://www.aphis.usda.gov/biotechnology/not_reg.html)).
- Pioneer. (2011b) Petition for the Determination of Nonregulated Status for Insect-Resistant and Herbicide-Tolerant 4114 Maize. Submitted by N. Weber, Registration Manager. Johnston, IA: Pioneer Hi-Bred International, Inc. Retrieved 9 November 2011, from
- Pioneer. (2012) Environmental Report for the Determination of Nonregulated Status for Insect-Resistant and Herbicide-Tolerant 4114 Maize. Submitted by Aimee Hyten. Johnston, IA: Pioneer Hi-Bred International, Inc. Retrieved 10 February 2012, from
- Pioneer. (2013a) 2013 Corn Hybrid-Herbicide Management Guide. Dupont-Pioneer. Retrieved from [https://www.pioneer.com/CMRoot/Pioneer/US/products/stewardship/2013\\_corn\\_herbicide\\_guide\\_ProdList.pdf](https://www.pioneer.com/CMRoot/Pioneer/US/products/stewardship/2013_corn_herbicide_guide_ProdList.pdf).

- Pioneer. (2013b) Weed Resistance Management. Dupont-Pioneer. Retrieved from <https://www.pioneer.com/home/site/us/products/stewardship/weed-management/>.
- Prince JM, Shaw DR, Givens WA, Owen MDK, Weller SC, Young BG, Wilson RG, and Jordan DL. (2012) Benchmark Study: IV. Survey of Grower Practices for Managing Glyphosate-Resistant Weed Populations. *Weed Technology*, 26(3), 543-548.
- Reddy KN, Zablotowics RM, Bellaloui N, and Ding W. (2011) Glufosinate Effects on Nitrogen Nutrition, Growth, Yield, and Seed Composition in Glufosinate-Resistant and Glufosinate-Sensitive Soybean. *International Journal of Agronomy*.
- Rieger MA, Lamond M, Preston C, Powles SB, and Roush RT. (2002) Pollen-Mediated Movement of Herbicide Resistance between Commercial Canola Fields. *Science*, 296, 2386-2388.
- Ronald P and Fouche B. (2006) Genetic Engineering and Organic Production Systems. . Oakland, CA: University of California, Division of Agriculture and Natural Resources. Retrieved November 8, 2010, from <http://anrcatalog.ucdavis.edu/pdf/8188.pdf>.
- Ruhland M, Engelhardt G, and Pawlizki K. (2004) Distribution and metabolism of D/L-, L- and D-glufosinate in transgenic, glufosinate-tolerant crops of maize (*Zea mays* L ssp *mays*) and oilseed rape (*Brassica napus* L var *napus*). *Pest Management Science*, 60(7), 691-696.
- Tabashnik BE, Gassmann AJ, Crowder DW, and Carriere Y. (2008) Insect resistance to *Bt* crops: Evidence versus theory. *Nature Biotechnology*, 26(2), 199-202.
- Tabashnik BE and Gould F. (2012) Delaying Corn Rootworm Resistance to *Bt* Corn. *Journal of Economic Entomology*, 105(3), 767-776.
- Then C. (2010) Risk Assessment of Toxins Derived from *Bacillus thuringiensis*--Synergism, Efficacy, and Selectivity. *Environmental Science and Pollution Research*, 17, 791-797.
- US-EPA. (2010) Terms and Conditions for *Bt* Corn Registrations. Office of Pesticide Programs, U.S. Environmental Protection Agency. Retrieved September 30, 2010, from
- USDA-AMS. (2007) National Organic Program Q and A. Retrieved from
- USDA-AMS. (2010) National Organic Program. Agricultural Marketing Service, United States Department of Agriculture. Retrieved November 23, 2010 from <http://www.ams.usda.gov/AMSv1.0/nop>
- USDA-APHIS. (2010) National Environmental Policy Act Decision and Finding of No Significant Impact: Pioneer Hi-bred International High Oleic Soybean DP-305423-1 Riverdale, Maryland: United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from
- USDA-ERS. (2011) Organic Prices. United States Department of Agriculture, Economic Research Service. Retrieved October 2011, 2011 from
- Vencill WK, Nichols RL, Webster TM, Soteris JK, Mallory-Smith C, Burgos NR, Johnson WG, and McClelland MR. (2012) Herbicide Resistance: Toward an Understanding of Resistance Development and the Impact of Herbicide-Resistant Crops. *Weed Science*, 60(sp1), 2-30.
- Whitworth RJ, Michaud JP, and Davis HN. (2013) Corn Insect Management. Kansas State University. Retrieved from
- Young BG, Gibson DJ, Gage KL, Matthews JL, Jordan DL, Owen MDK, Shaw DR, Weller SC, and Wilson RG. (2013) Agricultural Weeds in Glyphosate-Resistant Cropping Systems in the United States. *Weed Science*, 61(1), 85-97.

